

2011 Database

S. NO.	File . No.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	29/Misc/14/2010-DC(2)	M/s. Embrace, 1902 Divisadero Street, San Francisco, CA 94115, USA	1. EIW 2010-002	Using Embrace Infant in Low birth Weight Neonates	Not Regulated	1/13/2011
2	29/Misc/3/2010-DC(82)	M/s. Precision Coatings Pvt. Ltd., 101, Prince's Centre, 6/3, New Palasia, Indore-452001 (M.P)	1. Non-woven fabric adhesive coated rolls		Regulated	1/31/2011
3	29/Misc/3/2010-DC(84)	M/s. Jindal Medical & Scientific Instruments Company (Pvt.) Ltd., C-53A, Mansarover Garden, New Delhi-110015	1. Sea Tangle Tents (Laminara Tents) a Cervical Dilator		Not Regulated	1/31/2011
4	29/Misc/3/2010-DC(83)	M/s. Medicare Products Inc., C-53 A, Mansarover Garden, New Delhi-110015	1. Sea Tangle Tents (Laminara Tents) a Cervical Dilator		Not Regulated	1/31/2011
5	29/Misc/3/2010-DC(86)	M/s. Inshitra Medical Pvt. Ltd., 1201, Bldg. No. 15, Indradarshan, Phase II, Near Millat Nagar, Andheri (W), Mumbai-400053	1. Hernia repair implants		Regulated	1/31/2011
6	29/Misc/3/2011-DC(01)	The Addl. Drugs Controller, Drugs Control Department, Government of Karnataka, Place Road, Bangalore-01	1. Surgical Mesh for Hernia repai and Non-woven Microporous surgical Tapes		Regulated	1/31/2011
7	29/Misc/14/2010-DC(3)	M/s. Cardiomedics Inc., 7 Whatney, Suite B, Irvine, CA 92618	1. Cardiasist External Counter Pulsation (ECP) System		Not Regulated	2/4/2011
8	29/Misc/3/2011-DC(9)	Sh. Ram Chnder, Under Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Shastri Bhawan, New Delhi	1. Adult Diaper		Not Regulated	2/14/2011
9	4-MD/CT-56/2010-DC	M/s. Max Neeman International Limited, Max House, Ground Floor, 1 Dr. Jha Marg, Okhla Phase III, New Delhi-110020	1. Check-Cap's P1 Capsule System in Patients eligible for CRC screening		Not Regulated	2/18/2011

10	29/Misc/3/2011-DC(04)	M/s. Mitra Industries (P) Ltd., 14/4, Delhi-Mathura Road, Faridabad-121003	1. Esophageal stents, Biliary stents, Colo-rectal Stens, Pyloric/Duodenal stents and Tracheobronchial stent		<u>Regulated</u>	2/18/2011
11	29/Misc/5/2011-DC (Fenwal)	M/s. Fenwal India Pvt. Ltd., Upper Ground Floor, Tower B, DLF Building No. 10, DLF Cyber City, DLF Phase II, Gurgaon-122002, Haryana	1. Thermogenesis AXP AutoXpress System		<u>Not Regulated</u>	2/23/2011
			2. Manual Bag Sets having Processing/Plasma bag with sterile docking input line and clot filter, RBC bag, freezing bag total capacity: 25ml, Cyroprotectant line with sterile filter an intergrated segments for sterile sample collection		<u>Regulated</u>	
12	29/Misc/3/2010-DC(77)	M/s. Nobel Biocare India Pvt. Ltd., "Fortune 2000" 1st Floor, 'C' Wing, Bandra-Kurla Complex Bandara (E) , Mumbai-40001	1. Custom made dental products 2. Dental tools and accessories		<u>Not Regulated</u>	3/7/2011
13	29/Misc/3/2010-DC(93)	M/s. Win International Networks, Block 705, # 03-2569, Ang Mo Kio Avenue 8, Singapore 560705	1. Air purifying 'I SIG' (Air Filter + Mouth Flavourer)		<u>Not Regulated</u>	3/7/2011
14	29/Misc/3/2010-DC(96)	Dr. Sambhav Shah (M.S. Orthopaedic), 404, Simla House, E Block, Nepensea Road, Mumbai-400036	1. Humazone Machine		<u>Not Regulated</u>	3/8/2011
15	29/Misc/3/2011-DC(13)	M/s. Confident Sales India Pvt. Ltd., No. 47, 2nd Floor, Pete Channappa Indl. Estate Kamakshipalya, Magadi Road, Bangalore-560079	1. Synthetic Bone Graft Substitute (Bone Medik)		<u>Regulated</u>	3/10/2011

16	29/Misc/3/2011-DC(14)	M/s. Romsons Juniors India Unit-II, C-1 Foundry Nagar, Agra-282006	1. Non-Sterile bulk needles ready for sterilization and packing		<u>Regulated</u>	3/15/2011
17	29/Misc/3/2010-DC(87)	M/s B Braun Medical (India) Pvt. Ltd., III Floor, 23-A, Shivaji Marg, Najafgarh Road, New Delhi-110015	1. Orthopilot Navigation System		<u>Not Regulated</u>	3/15/2011
18	29/Misc/3/2011-DC(31)	M/s. Truskin Gloves Pvt. LTD., Plot No. 14C, Cochin Special Economic Zone, Kakkanad, Cochin-682037	1. Sterile Surgical Gloves		<u>Not Regulated</u>	4/6/2011
19	29/Misc/3/2011-DC(33)	Swedish Trade Council, C/o Embassy of Sweden, Nyaya Marg, New Delhi-110021	1. BIP Foley Catheter		<u>Regulated</u>	4/6/2011
20	29/Misc/3/2011-DC(32)	M/s. Rihim Pharma Consultancy Pvt. Ltd., 518-519, 5th Floor, Ring Road Mall, Mangalam Place, Sec-3, Rohini, New Delhi-110085	1. Blood Bags		<u>Regulated</u>	4/6/2011
21	29/Misc/3/2011-DC(37)	Sh. Sudhir Kumar, Under Secretary to Government of Inida, Nirman Bhavan, New Delhi	1. KKT Treatment Technology		<u>Not Regulated</u>	4/18/2011
22	29/Misc/3/2011-DC(28)	Mr. I.K. Vijay, Swedish Trade Council, C/o Embassy of Sweden, 4-5 Nyaya Marg, Chanakyapuri, New Delhi 110021	1. Components - Transmitter, inserter and receiver of Dexcom TM Seven [®] PLUS Continuous Glucose Monitoring System		<u>Not Regulated</u>	4/18/2011
			2. Sensor		<u>Regulated</u>	
23	31-731-MD/2009-DC End. 01	M/s. Baxter (India) Private Limited, 2nd Floor, Tower C, Building 8, DLF Cyber City, DLF, Phase II, Gurgaon-122002	1. Xenium LF Dialyzers		<u>Not Regulated</u>	4/18/2011
24	31-731-MD/2009-DC	M/s. Baxter (India) Private Limited, 2nd Floor, Tower C, Building 8, DLF Cyber City, DLF, Phase II, Gurgaon-122002	1. CA-HP Dialyzer		<u>Not Regulated</u>	4/18/2011
25	29/Misc/13/2011-DC(4)	M/s. Boston Scientific International B.V, 100 A, The Capital Court, Old Palme Marg, Munirka, New Delhi-110067	1. OPTI-MIND clinical outcomes of Pacemaker Patients acc. to pacing modality and primary indications.		<u>Not Regulated</u>	4/25/2011

26	29/Misc/13/2011-DC(5)	M/s. Biotronik Medical Devices India Pvt. Ltd., 101-106, Plot No. 14, LSC Kalkaji, New Delhi-110019	1. REMOTE-EVIA Registry for Pacemaker Offering Therapy Enhancement-EVIA		<u>Not Regulated</u>	4/25/2011
27	29/Misc/10/2010-DC (United Poly Eng.)	M/s. Untied Poly Engineering Pvt. Ltd., Okhla Industrial Area, Phase-II, New Delhi-110020	1. Medical Utensils and Hospital Furniture		<u>Not Regulated</u>	4/26/2011
28	29/Misc/5/2011-DC(41)	Dr. N.K. Agarwal Deputy Director Gernal (Ophth), DGHS Nirman Bhawan, New Delhi	1. Contact Lens Cleaning Solution		<u>Not Regulated</u>	5/5/2011
29	29/Misc/3/2011-DC(46)	Allwing Lifecare, 4, Damji Shamji Ind. Complex, Off. M.C. Road, Andheri (East), Mumbai-400093	1. Tranfusion Set 2. Infusion Set 3. Scalp Vein Infusion Set 4. A.V. Fistula Needle 5. Blood Line Tubing		<u>Regulated</u>	5/30/2011
30	29/Misc/5/2011-DC (M/s. Mediglobe System)	M/s. Mediglobe Systems, #2 Swamibathan Street, Ramalingapuram, Chennai-600012	1. Multi Sample Needle 22G 1 2. Multi Sample Needle 21G 1 3. Multi Sample Needle 20G 1.5 4. Multi Sample Needle 22G 3/4		<u>Regulated</u>	6/1/2011
31	29/Misc/3/2011-DC(47)	M/s. Sisco Medical Devices (P) Ltd., 6/153, Mount Poonamallee Road, Chennai 600089	1. Bulk Pack unsterile needles import vide BOE No. 817509		<u>Regulated</u>	6/7/2011
32	29/Misc/14/2011-DC(7)	M/s. Max Neeman International Limited, Max House, Ground Floor, 1 Dr. Jha Marg, Okhla Phase III, New Delhi-110020	1. Digital Ballistocardiogram and Echocardiogram		<u>Not Regulated</u>	6/9/2011
33	29/Misc/3/2011-DC(22)	Mr. Labhesh V. Lunkad, 20/125, Anand Krupa, Civil Hudco, Near Jain Temple, Savedi Road, Ahmednagar, Maharashtra-414003	1. Magnetic Device		<u>Not Regulated</u>	6/9/2011
34	29/Misc/3/2011-DC (52)	Mr. Akash Chauhan, Senior Associate, India Law Officers, D-19, (GF), South Extension-I, New Delhi-49	1. Doc Laser		<u>Not Regulated</u>	6/9/2011

35	29/Misc/3/2011-DC(60)	Sh. RK Pathni, GP Capt, O i/c RC Cell, For DGAFMS Raksha Mantralaya, Karyalya Mahanideshak, Shashastra Sena Chikitsaa Sewa, M Block, New Delhi-110001	1. Filter without blood bag		Not Regulated	6/21/2011
36	29/Misc/3/2011-DC(61)	M/s. Friends Consolidation Ltd., #8-2-293/82/A/281-O, Road # 10B, Gayatri Hills, Jubilee Hills, Hyderabad- 500033	1. Haemostatic Pad		Regulated	6/21/2011
37	29/Misc/3/2011-DC(62)	M/s. G.S.T. Corporation, B-13, Okhla Industiral Area, Phase II, New Delhi-20	1. Veusable Veterinary Needles		Regulated	6/22/2011
38	29/Misc/3/2011-DC(73)	M/s. B. Braun Medical (India) Pvt. Ltd., III Floor, 23-A, Shivaji Marg, Najafgarh Road New Delhi-110015	1. Intravenous Infusion Administraion Sets		Regulated	7/5/2011
39	29/Misc/3/2011-DC(68)	S-Three Sales Intl. Pvt. Ltd., D-9, Jangpura Extension, New Delhi-110014	1. Safest Blood Samplling System		Regulated	7/5/2011
40	29/Misc/3/2011-DC(67)	M/s. PAT Pharma Consultants India Pvt. Ltd., Unit No. 2nd Floor, Vikas Surya Arcade, Plot No. 7, CU Block, Pitampura, Delhi-110088	1. Velumount		Not Regulated	7/5/2011
41	29/Misc/3/2010-DC(17)	M/s. Reevax Pharma Limited, 502 Rohini Apt. Srinagar Colony Road, Hyderabad-500073 AP	1. XOIN (A topical tissue adhesive)		Regulated	7/18/2011
42	29/Misc/14/2011-DC(8)	M/s. Max Neeman International Limited, Max House, Ground Floor, 1 Dr. Jha Marg, Okhla Phase III, New Delhi-110020	1. ALERTS (Angelmed for early recognition and treatment of STEMI)		Not Regulated	8/9/2011
43	29/Misc/3/2011-DC(86)	M/s. Nipro India Corporation Pvt. Ltd., 503/504 Sai Capital, Opp. ICC Tech Park, Senapati Bapat Road, Pune 411016	1. Dialyzer		Not Regulated	8/24/2011
44	29/Misc/3/10-DC(92)	M/s. Precision Coatings Pvt. Ltd., 101, Prince's Centre, 6/3, New Palasia, Indore-452001 (M.P)	1. I.V. Dressing by way of inclusion in the existing manufaccturing licesne		Regulated	9/6/2011
45	29/Misc/3/2011-DC(62)	M/s. G.S.T. Corporation, B-13, Okhla Industiral Area, Phase II, New Delhi-20	1. Reusable Veterinary Needles		Regulated	9/20/2011
46	29/Misc/3/10-DC(29)	M/s. Fresinius Kabi India Pvt. Ltd., Echelon Institutional Area, Plot No. II, Sector-32, Gurgaon-122001	1. Feeding Tubes: Freka Tube		Not Regulated	9/20/2011

47	29/Misc/3/2011-DC(97)	M/s. Ypsomed India Pvt. Ltd., 10/61/1 F, Kirti Nagar, Industiral Area, New Delhi-110015	1. Lancet Needles		Not Regulated	9/20/2011
48	29/Misc/3/2011-DC(105)	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, Near Picket, Secunderabad-500009 (A.P)	1. Ulthera System		Not Regulated	9/21/2011
49	29/Misc/3/2011-DC(104)	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, Near Picket, Secunderabad-500009 (A.P)	1. Viberec TM Penile Vibratory Stimulation device		Not Regulated	9/21/2011
50	29/Misc/3/2011-DC(54)	M/s. Becton Dickinson India Pvt. Ltd., 5th & 6th Floor, Signature Tower-B, South City-I, Gurgaon-122001	M/s. BD Oralp TM Oral Dosing Dispenser		Not Regulated	9/21/2011
51	29/Misc/3/2011-DC(91)	M/s. 12iHealth Trading Pvt. Ltd., 413/414 Oxford Tower, 139 Old Airport Road, Kodihalli (Opp. Leela Place), Bangalore-560008	1. LungFlute		Not Regulated	9/27/2011
52	29/Misc/3/2011-DC(98)	M/s. Swedish Trade Council C/o Embassy of Sweden, New Delhi	1. Digital Cardio Rhythm Analyzer-Dinamika		Not Regulated	9/30/2011
53	29/Misc/3/2011-DC(78)	M/s. Sagar Fossil Fuel Technologies Private Limited, 257-A, 1st Floor, Hauz Rani Market, Press Enclave Road, New Delhi-110017	1. Orthopaedic Bandages (For External Use)		Regulated	9/30/2011
54	29/Misc/3/2011-DC(94)	Dr. K.M. Cherain's, Froniter Lifeline Hospital (A unit of Frontier Lifeline P. Ltd.) R-30-C, Ambattur Industrial Estate Road, Chennai-600101	1. Organ Chamber		Not Regulated	9/30/2011
55	29/Misc/3/2011-DC(93)	M/s. Allwin Lifecare, 4, Damji Shamji Industrail Com. Off Mahakali Caves Road, Andheri (East), Mumbai-400093, Maharashtra	1. Blood Collection Bags with Anticoagulant CPD A1. 2. Blood Collection Bags with Anticoagulant CPD SAGM. 3. Transfer Pack		Not Regulated	9/30/2011

56	29/Misc/3/2011-DC(112)	M/s. Lotus Surgical Pvt. Ltd., 4, Gitanjali, 1st Floor, Plot No. 116-A, Road No. 24-A, Sion (West), Mumbai-400022	1. Skin Staplers		<u>Regulated</u>	10/18/2011
57	29/Misc/3/2011-DC(120)	M/s. GST Corporation, B-13, Okhla Industrial Area, Phase-II, New Delhi-110020	1. Latex Male Catheter/Connector		<u>Regulated</u>	10/25/2011
58	29/Misc/3/2011-DC(113)	M/s. Combindia Biotech Kits (Pvt.) Ltd/. 208, Partik Industrial Estate, Mulund- Goregaon Link Road, Next to Wockhardt Hospital, Mulund (West), Mumbai-400078	1. Evacuated Blood Collection Needles Multi Drawing Needles 22x1		<u>Regulated</u>	10/25/2011
59	29/Misc/3/2011-DC(108)	M/s. Nirmal Biotech, E/2, Manjapur, Township No. 1, Opp. Sandalwood, Soc. Manjapur, Vadodara-390011, Gujarat	1. Silicone Oil and Intraocular Gases		<u>Regulated</u>	10/25/2011
60	29/Misc/3/2011-DC(116)	M/s. Allergan India Private Limited, Lvel-2, Prestige Obelisk No. 3, Kasturba Road, Bengaluru-560001	1. Eyegiene		<u>Not Regulated</u>	10/25/2011
61	29/Misc/3/2011-DC(50)	M/s. LIV Medica, 2-395, Mookamblga Nagar, Kattupakkam, Chennai-600056	1. First Aid Kits for exports		<u>Regulated</u>	11/11/2011
62	29/Misc/3/2011-DC(92)	M/s. Akraya Energy International Pvt. Ltd., 621, Galleria Office Complex, DLF Phase IV, Gurgaon-122002	1. Cold Dry (Ice Sterile)	Use for Analgesic, Anti-inflammatory, Anti-edema action	<u>Regulated</u>	11/11/2011
63	29/Misc/3/2011-DC(119)	M/s. Global Trade Resources 212, Ansal Chember-II, Bhikhaji Cama Place, New Delhi-110024	1. Fever Cooling Patch		<u>Regulated</u>	11/11/2011
64	29/Misc/3/2011-DC(106)	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, Near Picket, Secunderabad-500009 (A.P)	1. CellTrans ABT Post-operative Blood Transfusion System		<u>Regulated</u>	11/21/2011
65	29/Misc/3/2011-DC(124)	M/s. LIV Medica, 2-395, Mookamblga Nagar, Kattupakkam, Chennai-600056	1. Adhesive Bandages		<u>Regulated</u>	11/21/2011
66	29/Misc/3/2011-DC(118)	M/s. Viridis Biopharma Pvt. Ltd., 6/10 Jogani Industrial Complex, V.N. Purav Marg,;, Chunabhatti, Mumbai-022	1. Substance P	As wound healing devices	<u>Regulated</u>	11/21/2011
67	29/Misc/3/2010-DC(99)	M/s. Smith & Nephew Healthcare Pvt. Ltd., 203 B, Dynasty Business Park, Andheri Kurla Road,	1. IV 3000 and OpSite Flexifix		<u>Not Regulated</u>	11/21/2011

68		Andheri (East), Mumbai-400059	2. Opsite Incite and Opsite Post-op		Regulated	
69	29/Misc/3/2011-DC(127)	M/s. Bhabha Atomic Research Centre Hospital Anushaktinagar, Mumbai-400094	1. Used for Manula removal of stool/faeces		Not Regulated	11/22/2011
70	29/Misc/14/2011-DC(10)	M/s. Max Neeman International Limited, Max House, Ground Floor, 1 Dr. Jha Marg, Okhla Phase III, New Delhi-110020	1. Multi Acting Nasal particle Blocker (MAPB)		Not Regulated	11/22/2011
71	29/Misc/10/2010-DC (S.H. Pitkar Orthotools)	Sh. Narendra Vashista, Foreign Trade Development Officer, Ministry of Commerce & Industry, Government of India, DGFT, Udyog Bhavan, New Delhi	1. Othopaedic Implants		Regulated	11/24/2011
72	29/Misc/3/2011-DC(126)	M/s. Smith & Nephew Healthcare Pvt. Ltd., 203 B, Dynasty Business Park, Andheri Kurla Road,	1. PICO Pump 2. Dressing and Stirips		Not Regulated Regulated	12/7/2011
73	29/Misc/3/2011-DC(120)	Mr. B.S. Kain, (Section Officer) Nirman Bhavan, New Delhi	1. Latex Male Connector		Not Regulated	12/9/2011
74	29/Misc/3/2011-DC(121)	Mr. B.S. Kain, (Section Officer) Nirman Bhavan, New Delhi	1. Re-Usable, Non-Sterile Needle for suture		Not Regulated	12/9/2011
75	29/Misc/3/2011-DC(135)	The ADC(I), CDSCO Sub Zonal Ahmedabad, Aire Cargo Complex Old Terminal Building, Airport Ahmedabad-380016	1. Dental Implants		Regulated	12/9/2011
76	29/Misc/3/2011-DC(121)	M/s. G.S.T. Corporation, B-13, Okhla Industiral Area, Phase II, New Delhi-20	1. Re-Usable, Non-Sterile Needle for suture		Not Regulated	12/9/2011
77	29/Misc/3/2011-DC(134)	M/s. Stericat Gutstrings(P) Ltd., 169, Sector-4, IMT Manesar, Gurgaon, Haryana-122050	1. Sterile Monofilament Polypropylene Mesh		Regulated	12/9/2011
78	29/Misc/3/2011-DC(144)	M/s. A S Smokefree Electorinc Cigarette Pvt. Ltd., G-4, Southx-2, New Delhi-110048	1. Electronic Cigarette		Not Regulated	12/9/2011
79	29/Misc/3/2011-DC(96)	M/s. Abbott Medical Optics Private Limited, The Masterpiece, Level-5, Golf Course Road, Sector-54, Gurgaon-122002 Haryana	1. Contact Lens Care Products	Used for cleaning of proteings from contact lenses	Not Regulated	12/9/2011
80	29/Misc/3/2011-DC(138)	M/s. Wellset Ortho, No. 402, Gokul Classic, Above Karur Vysya Bank, Nizampet Road, Hyderabad-500072	1. Fiberglass Casting Tape 2. Water repellent Underpad		Regulated Not Regulated	12/9/2011

81	29/Misc/3/2011-DC(128)	M/s. One Touch Medical Products (P) LTD., 2h/78, Bahadurpur Housing Colony Kankarbagh, Patna-800026	1. Non Sterile Needle	Ready for sterilization, labeling and packing	Regulated	12/9/2011
82	29/Misc/3/2011-DC(141)	M/s. Fresenius Kabi India Pvt. Ltd., A-3, MIDC, Rajangaon, Ganpati Tal. Shirur, Dist. Pune	1. Giving set for infusion pump- Volumet lines	Used for infusion of I.V. Fluid/ Durgs etc	Regulated	12/20/2011
83	29/Misc/3/2011-DC(139)	M/s. B. L. Lifesciences Pvt. Ltd., A-245, Okhla Industrial Area, Phase-I, New Delhi-110020	1. HYPOTHERMOSOL 2. CRYOSTOR 3. BLOODSTOR	1. Used for preservation of cells 2. Used for protective environment for cells and 3. Used for cryopreservation of stem cells	Not Regulated	12/20/2011
84	29/Misc/3/2011-DC(137)	Sh. R. K. Pathni (G.p. Capt) O i/c RC Cell Raksha Mantralaya, Karyalaya Maha Nideshak, Sashastra Sena Chikitsa Sewa, 'M' Block, New	1. Vacuumised Tubes 2. Disposable Hypodermic Needles		Not Regulated Regulated	12/20/2011
85	29/Misc/3/2011-DC(148)	M/s. Manish Enterprises, 2/19, Bhuta Nivas, Dr. Ambedkar Road, Matunga, Mumbai-400019	1. I.V. Fixator	Used to holds I.V. Cannula	Not Regulated	12/23/2011
86	29/Misc/3/2011-DC(151)	M/s. Smith & Nephew Healthcare Pvt. Ltd., 203 B, Dynasty Business Park, Andheri Kurla Road, Andheri (East), Mumbai-400059	1. Trigen Sureshot Distal Targeting System		Not Regulated	12/30/2011
87	29/Misc/3/2011-DC(149)	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, Near Picket, Secunderabad-500009 (A.P)	1. VibeX 2. Avendro Inc.'s KXL Systems's		Regulated Not Regulated	12/30/2011

2012 Dat e	S. NO.	File . No.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
	1	29/Misc/3/201 1-DC(153)	M/s. Beauvana Biotech Pvt. Ltd., 6/7 A, Selva Ratna Vinayagar Ave, Cart Tract Road, Velchery,	1. Intermesh Soft Lift, Intermesh T-1, Biomesh-P1, 4D-DOME, BIOMESH Soft-P9, BIOMESH Soft Prolapse, BIOMESH Light-P8, BIOMESH-A2, CABS-AIR composite and Biomesh Soft Prolaps-Cystocele Hernia Mesh		<u>Regulated</u>	1/3/2012
	2	29/Misc/3/201 1-DC(123)	M/s. Beauvana Biotech Pvt. Ltd., 6/7 A, Selva Ratna Vinayagar Ave, Cart Tract Road, Velchery,	1. Bioring Gastric Lap Brand		<u>Regulated</u>	1/3/2012
	3	29/Misc/3/201 1-DC(72)	The Director, Directorate of Food & Drugs Admn., Old I.P.H.B. Complex, Altinho, Panji-Goa	1. Smallbore Y- Connector Extension Set, 2 Needle- Free Valves, Spin male luer lock 2. Smallbore Tri- port extension set, 3 needle - Free Valves, Fixed male luer lock		<u>Regulated</u>	1/3/2012
	4	29/Misc/3/201- DC(163)	M/s. Pacific Bridge Medical India, 117, Pratap Complex, Partap Market, Munirka, New Delhi- 110067	1. Heart Mate - II Left Ventricular Assist System (LVAS)		<u>Not Regulated</u>	1/17/2012
	5	29/Misc/3/201 1-DC(168)	M/s. Medicaid Agencies, 204, Shivlok House-II, Karmapura Comm. Complex, New Delhi-110015	1. Bone Injection Gun		<u>Regulated</u>	1/24/2012
	6	29/Misc/3/201 1-DC(169)	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kaguda, Near Picket, Secunderabad- 500009 (A.P)	1. Spiro PD	Used for measurement of air flow & volume	<u>Not Regulated</u>	1/24/2012
	7	29/Misc/3/201 1-DC(167)	M/s. A. B. Dental Devinces Ltd., Park Hanada, 3 Habosem St. Ashdod Israel	1. Dental Implant and Abutments		<u>Regulated</u>	1/24/2012

8	29/Misc/3/201 1-DC(152)	M/s. Sanzyme Ltd., Plot No. 13, Sagar Society, Road No. 2, Banjara Hills, Hyderabad-500034	1. Invo Cell™	Use in preparing, storing, manipulation or transferring	<u>Not Regulated</u>	1/31/2012
9	29/Misc/3/201 1-DC(166)	M/s. Indian Hygiene Products Co., 176, Bara Bazar, Kolkata-6	1. Ribbel Ultra Comfort Adult Diaper		<u>Not Regulated</u>	2/13/2012
10	29/Misc/3/201 1-DC(162)	M/s. B. Braun Medical Indian Pvt. Ltd., II Floor, 23-A, Shivji Marg, Najafgarh Road, New Delhi- 110015	1. Neuro- Patch and Lyoplant	Used as a Dura substitute in any intracranial and	<u>Regulated</u>	2/14/2012
11	29/Misc/3/201 1-DC(109)	M/s. B. Braun Medical Indian Pvt. Ltd., II Floor, 23-A, Shivji Marg, Najafgarh Road, New Delhi- 110015	1. YASARGIL Aneursym Clip		<u>Regulated</u>	2/14/2012
12	29/Misc/3/201- DC(170)	M/s. Gentech Laboratories Ltd., Gala No. 401, 4th Floor, Marol Bhawan, Marol Co-op Indl Estate, J.B. Nagar, Andheri-East, Mumbai-400059	1. Injex Needle Free Injection Devices		<u>Regulated</u>	2/14/2012
13	29/Misc/3/201 2-DC(02)	M/s. Synthes Medical Pvt. Ltd., Plot No. 118-P, Sector-44, Gurgaon	1. Customs made Implant - PEEK bone replacement Implant (Non-sterile)		<u>Not Regulated</u>	2/27/2013
14	29/Misc/3/201 2-DC(21)	Mr. P.B.N. Prasad, Deputy Drugs Controller (I), CDSCO, South Zone Second Floor, Shastri Bhawan Annexe, 26, Haddows Road, Chennai- 600006	1. Non sterile Bulk Syringes W/o Needle		<u>Regulated</u>	3/1/2012
15	29/Misc/3/201 2-DC(15)	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, Near Picket, Secunderabad- 500009 (A.P)	1. EHY - 2000 Plus		<u>Not Regulated</u>	3/1/2013
16	29/Misc/3/201 2-DC(18)	M/s. NXT Medical Devices Pvt. Ltd., 19, 1st Street, Parthasarathy Nagar, Adambakkam, Chennai-88	1. Dru Inhaler without any Drugs	Used for asthma patients	<u>Not Regulated</u>	3/1/2012
17	29/Misc/3/201 1-DC(150)	M/s. Medsurge Ind Private Limited, New No. 7, Old No. 4, 1 Cross Street, Shastri Nagar, Adyar, Chennai-600020	1. Surgical Disposable Products: Plastibell, Amni Hook, Urine Bag, Umbilical Cord Clamp		<u>Not Regulated</u>	3/1/2012

18	29/Misc/3/2012-DC(10)	M/s. Buoyant Medicos, 47/12, LGF, Old Rajinder Nagar, New Delhi	1. Hematrix- active patch wound dressing for immediate Haemostasis	Used on external wounds to stop even severe arterial or venous bleeding	<u>Regulated</u>	3/1/2012
19	29/Misc/3/2012-DC(11)	M/s. Nirma Limited, Nirma House, Ashram Road, Ahmedabad-380009	1. Non sterile Bulk Syringes		<u>Regulated</u>	3/1/2012
20	29/Misc/3/2012-DC(14)	M/s. U & N Commercial Consultancy, D003 Casa Ansal Apartments, No. 18, Bannerghatta, Bangaluru - 560076	1. Bioelectrical Impedance Analysis (BIA) Devices		<u>Not Regulated</u>	3/1/2012
21	29/Misc3/2012-DC(08)	M/s. Delhi Ey Zone Pvt. Ltd., D-114, (G.F.), Lajpat Nagar-I, New Delhi-110024	1. Latician Retinal Implants	Used in the treatment of retinal detachments	<u>Not Regulated</u>	3/1/2012
22	29/Misc/3/2012-DC(12)	M/s. KMS Medisurgi Pvt.Ltd., 44, Mangaldas Road, Bulakhidas Bldg, Gr. Floor, Mumbai- 400 002	1. Micro Foam Surgical Tape	Used for securing dressings on challenging areas	<u>Not Regulated</u>	3/6/2012
23	29/Misc/3/2012-DC(16)	M/s. Bausch + Lomb India Pvt. Ltd., 2nd Floor, Tower A, Buliding No. 8, DLF Phase II, DLF Cyber City, Gurgaon - 122002	1. Lens Care Solutions and Soft Contact Lenses		<u>Not Regulated</u>	3/6/2012
24	29/Misc/10/2012-DC-1 (GSK)	Sh. Samir Sinha, Foreign Trade Development Officer, Ministry of Commerce and Industry, DGFT, Udyog Bhavan, New Delhi	1. Gauze Rolls	Used for Wound dressings (Surgical Dressings)	<u>Regulated</u>	3/6/2013
25	29/Misc/3/2011-DC(143)	M/s. 3 M India Limited, Plot Nos. 48-51, Electronics City, Hosur Road, Bangalore-560100	1. Fluid Warming system	Used for to generate temperature	<u>Not Regulated</u>	3/9/2013
26	29/Misc/3/2011-DC(143)	M/s. 3 M India Limited, Plot Nos. 48-51, Electronics City, Hosur Road, Bangalore-560100	1. 3M Ranger Blood	Disposible I.V. Administration set (Ranger lood)	<u>Regulated</u>	3/9/2013
27	29/Misc/3/2012-DC(25)	M/s. Medi Globe Systems, # 22, Pandaram Street, Purasaiwakkam, Chennai- 600007	1. Tube Holder and Vacuum Tube		<u>Not Regulated</u>	3/29/2012
28	29/Misc/3/2012-DC(25)	M/s. Medi Globe Systems, # 22, Pandaram Street, Purasaiwakkam, Chennai- 600007	1. Double Ended Needle (Multi sample Needle)		<u>Regulated</u>	3/29/2012
29	29/Misc/3/2012-DC(30)	M/s. Medihauze International, Shreedharma, 2676/20, 11th Main, D Block, 2nd Stage Rajajingar, Bangalore- 560010	1. NexTemp Single use Clincial thermometer, Traxit Wearable Thermomr, NexTemp Reusable Clinical Thermometer with a Carrying Card Holder, NexTemp Plus Rectal Sheath, Nextemp Standard Clinical Oral Thermometer		<u>Not Regulated</u>	4/3/2012

30	29/Misc/3/201 2-DC(24)	M/s. 3 M India Limited, Plot Nos. 48-51, Electronics City, Hosur Road, Bangalore-560100	1. Scotchcast Premium Casting Tape		<u>Regulated</u>	4/3/2012
31	29/Misc/3/201 2-DC(31)	M/s. Alcon Laboratories (I) Pvt. Ltd., No. 3, 5th Floor, RM Infinity Tower D, Unit No. 502, Old Madras Road, Benniganahallo, Bangalore-560016	1. Acrysof Restor 1Q Multifocal Toric Intraocular Lens		<u>Not Regulated</u>	4/3/2012
32	29/Misc/5/201 2-DC(09)	Dy. DDC (I), CDSCO (North Zonr) 1st Floor, Central Govt. Office Building- I, Kamla Nehru Nagar (Central Govt. Enclave), Hapur Road, Ghaziabad- 201002	1. Auction of BioloX forte (An Orthopaedic Implant)		<u>Regulated</u>	4/3/2012
33	29/Misc/3/201 2-DC(07)	M/s. In Vitro Medical Solutions (P) Ltd., E-291, Sarita Vihar, New Delhi-110076	1. Vacuum & non vacuum tubes, Lencet Tourniquets and Needle Holder		<u>Not Regulated</u>	4/4/2012
34	29/Misc/3/201 2-DC(07)	M/s. In Vitro Medical Solutions (P) Ltd., E-291, Sarita Vihar, New Delhi-110076	1. Multi Sample Needle (Pen Type and Butterfly Type)		<u>Regulated</u>	4/4/2012
35	29/Misc/3/201 2-DC(09)	M/s. Juno Pharma, 3rd Floor, Harith Arcade, D. No. 3- 100/2/B, Survey No. 277, Nizampet Road, Hyderabad-500090	1. Actipatch	Use for relief o f Acute and chronic pain, Inflammation and swelling, stains and sprains	<u>Regulated</u>	4/4/2012
36	29/Misc/14/20 11-DC(12)	M/s. St. Jude Medical India Pvt. Lt., No. 1-11-250 A, Matarani Sensation, Begumpet, Hyderabad 500016, India	1. Pacemakers 2. Leads		<u>Not Regulated</u>	4/10/2012
37	29/Misc/3/201- DC(56)	M/s. UP Dental Products Pvt. Ltd., 107, 1st Floor, Sai Commercial Centre, Mumbai - 400088	1. Porcelain Etch & Silane 2. Sable Seek 3. VALO 4. Sof-Tray Classic Sheets 5. Ultracal 6. Ultra-blend plus 7. File-Eze	1. For Etching Porcelain and Preparation for bonding. 2. Indicator Stain 3. Curing Light 4. Tray Fabricating Sheet 5. Lining and Capping 6. Cavity Liner 7. Solution for cleaning and chelating a Root Canal	<u>Not Regulated</u>	4/10/2012

38	29/Misc/3/201 2-DC(45)	M/s. Varian Medical Systems India Software Pvt. Ltd., Tower XL, Level 7, Cybercity Magarpatta, Hadapsar, Pune-411013	1. Calypso	Used to detect cancer organ movement during radiation treatment	<u>Not Regulated</u>	4/10/2012
39	29/Misc/3/201 2-DC(41)	M/s. SkinCare Surgipharma Pvt. Ltd., Shop No. 7, Salamat Mansion (Opp. Ravindra Natya Mandir), Sayani Road, Prabhadevi, Mumbai- 400025	1. Orafts (Bone Graft) 2. RediGrafts (Bone Graft) 3. FlexiGrafts (Tissue Graft)		<u>Not Regulated</u>	4/10/2013
40	29/Misc/3/201 2-DC(43)	M/s. Arun & Co., 601/A & 602/B Polaris, off Marol Maroshi Road, Marol, Andheri (East), Mumbai-400059	1. Diagnostic Enzymes- Panicillinase 2. B-Lactamase	Used in Laboratory	<u>Not Regulated</u>	4/17/2012
41	29/Misc/3/201 2-DC(03)	M/s. ClinTech India, Plot # 222, Sabari Aangan, 11th Road, Chembur, Mumbai-400071	1. Hemo Rite	Used is for treatment of hemorrhoids by Cryotherapy	<u>Not Regulated</u>	4/17/2012
42	29/Misc/3/201 1-DC(57)	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kagguda, Near Picket, Secunderabad- 500009 (A.P)	1. SPATZ®Adjustable Balloon System	Used for weight loss by partially filling in the stomach and Provent therapy NASAL Cannula Diagnostic Kit consisting of provent nasal cannula & provent Device- intended for the treatment of in obstructive sleep apnea	<u>Regulated</u>	4/17/2012
43	29/Misc/3/201 1-DC(57)	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kagguda, Near Picket, Secunderabad- 500009 (A.P)	2. Epiflo® Transdermal Continous oxygen therapy	Intended to deliver pure oxygen to the wounds	<u>Not Regulated</u>	4/17/2012
44	29/Misc/14/20 12-DC(2)	M/s. Vascular Concepts Ltd., 7C, Doddaballapur Industial Estate, Doddaballapur, Bangalore-561203	1. Pronova CC-Sirolimus Eluting Stent		<u>Regulated</u>	4/18/2012
45	29/Misc/14/20 12-DC(1)	M/s. Vascular Concepts Ltd., 7C, Doddaballapur Industial Estate, Doddaballapur, Bangalore-561203	1. Pronova XR-Sirolimus Eluting Stent		<u>Regulated</u>	4/18/2012

46	29/Misc/3/2012-DC(46)	M/s. Chayagraphics (India) Pvt. Ltd., #249, 4th Main Road, Chamarajpet, Bangalore-560018	1. Syringes and Low Pressure Disposable for CT/MR/Angio Injectors	Used in the contrast media injectors, hence Syringes and Low Pressure Disposable for CT/MR/ Angio Injectors	<u>Regulated</u>	4/24/2012
47	29/Misc/3/2012-DC(51)	M/s. Int'l Marketing & Development, The Bucley Group LLC, 4455 South Group Padre Island Drive Suite #5, Corpus Christi, TX 78411	1. Sharps Terminator TM	Destroys a wide range of disposable needles	<u>Not Regulated</u>	4/24/2012
48	29/Misc/3/2011-DC(111)	M/s. Kindegarten Rehab Suppliers, 14, M.P. Jain Compound Raheja Township, Mald (East), Mumbai-400097	1. Kinesio Tape	Involves taping over and around muscles to prevent over contraction	<u>Not Regulated</u>	4/24/2012
49	29/Misc/3/2011-DC(187)	M/s. Rejen Biomedical Pvt. Ltd., 401 Bhaveshwar Complex, Vikyavihar (W), Mumbai-86	1. Chemablate	Intended to ablate the endometrial lining of the uterus in women the Menorrhagia	<u>Regulated</u>	4/26/2012
50	29/Misc/3/2012-DC(36)	M/s. Span Healthcare Pvt. Ltd., Columbus Business Chambers, #17, 7th Temple Street, 15th Cross Malleswaram, Bangalore-56003	1. SCOUT DS Invasive Diabetes screening device	Intended to analyze the level of glucose in human blood	<u>Not Regulated</u>	4/26/2012
51	29Misc/3/2012-DC(27)	M/s. Care Fusion, Tower D, Second Level, DLF IT Park, Kishangarh, Chandigarh	1. SmartSite	Used as a self sealing connector	<u>Regulated</u>	4/26/2012
52	29/Misc/3/2011-DC(130)	M/s. B. Braun Medical Indian Pvt. Ltd., II Floor, 23-A, Shivji Marg, Najafgarh Road, New Delhi-110015	1. Infuvalve Back Check Valve	Used as a accessory for infusion therapy to prevent back flow into infusion lines	<u>Regulated</u>	4/26/2012

53	29/Misc/3/201 2-DC(47)	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, Near Picket, Secunderabad- 500009 (A.P)	1. Nanosonic Trophon EPR System	Consists of a multiple use instrument, combined with a single use disinfectant which is delivery form multi dose cartridge Hydrogen peroxide	<u>Not Regulated</u>	5/1/2012
54	29/Misc/3/201 2-DC(47)	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, Near Picket, Secunderabad- 500009 (A.P)	1. Nanosonic Trophon EPR System	Multi Cartridge of Hydrogen Peroxide Disinfectant	<u>Regulated</u>	5/1/2012
55	29/Misc/3/201 2-DC(55)	M/s. S.B. Medicare Pvt. Ltd., A-258, Defence Colony New Delhi-110024	1. Ligating Clips (Polymer/Titanium)	Intended for ligating of any tissue structures or vessels during operation for haemostasis	<u>Regulated</u>	5/1/2012
56	29/Misc/3/201 2-DC(53)	M/s. Synthes Medical Pvt. Ltd., Plot No. 118-P, Sector-44, Gurgaon	1. VBS S/M/L Vertebral Body Stenting System		<u>Not Regulated</u>	5/1/2012
57	29/Misc/3/201 2-DC(57)	Sh. Greh Pal Singh, 480, Double Story, (G.F). New Rajinder Nagar, New Delhi-110060	1. Minitype of Air Filtration Device, which may supply infection free air		<u>Not Regulated</u>	5/3/2012
58	31-188- MD/2006- DC(Re-Reg 2009)	M/s. Synthes Medical Pvt. Ltd., Plot No. 118-P, Sector-44, Gurgaon	1. Cable System	For Orthopaedic Trauma Surgery and Intended use as periprosthetic fractures, temporary reduction	<u>Regulated</u>	5/8/2012
59	29/Misc/14/20 12-DC (3)	M/s. Max Neeman International Limited, Max House, Ground Floor, 1 Dr. Jha Marg, Okhla Phase III, New Delhi-110020	1. Cyberonics Vagus Nerve Stimulation (VNS) therapy system		<u>Not Regulated</u>	5/8/2012
60	29/Misc/14/.20 12-DC(4)	M/s. Lumenis India Pvt. Ltd., Unit No. : 308-310, 3rd Floor, Suncity Business Tower, Sector-54, Golf Course Road, Guragaon-12202 Haryana	1. Light Sheer Duet		<u>Not Regulated</u>	5/15/2012

61	29/Misc/3/201 2-DC(01)	M/s. Eisai Pharmaceutical India Private Limited, 1st Floor, B Wing, Marwah Centre, Krishanlal, Marwah Marg, Andheri (East), Mumbai-400072	1. DC Bead & Bead Block		<u>Regulated</u>	5/23/2012
62	29/Misc/3/201 1-DC (171)	M/s. Millenium Biotch, J-6/98, Second Floor, Rajori Grden, New Delhi-110027	1. Comfort Bath, Comfort Shampoo Cap	Used for the purpose of cleansing human body or its part(s)	<u>Regulated</u>	5/23/2012
63	29/Misc/3/201 1-DC (171)	M/s. Millenium Biotch, J-6/98, Second Floor, Rajori Grden, New Delhi-110027	1. Antiseptic Body Washcloth, Comfort Shield Barrier Cloth		<u>Regulated</u>	5/23/2012
64	29/Misc/3/201 2-DC(56)	M/s. Delhi Ey Zone Pvt. Ltd., D-114, (G.F.), Lajpat Nagar-I, New Delhi-110024	1. Ferrara Ring an Intracorneal Implants	Used for correction of pathological tissue deformities of the cornea	<u>Not Regulated</u>	5/23/2012
65	29/Misc/3/201 2-DC(29)	M/s. Krisna Patient Care Systems India Pvt. Ltd., M-28, 3rd Floor, G K (Greater Kailash)-II, M- Block Market, New Delhi-110048	1. Drug Free Pain Relief TransCare Medical Devices-Ova, Itouch Eas, Itouch Sure, Itouch tone, Touch Tens, Mamatens, Sport Tens, and Ultima IF4160		<u>Not Regulated</u>	5/23/2012
66	29/Misc/3/201 2-DC(06)	M/s. Paul Hartmann Medical Private Limited, Regus Suburb Centre Private Ltd., Level-4, Dynasty Business Park, A-Wing, Andheri Kurla Road, Andheri (East), Mumbai	1. Various non woven compund/Multiplayer compound - Drape Sheets for various operations/ surgeries		<u>Regulated</u>	5/23/2012
67	29/Misc/3/201 2-DC(13)	M/s. 3 M India Limited, Plot Nos. 48-51, Electronics City, Hosur Road, Bangalore-560100	1. Tissue Adhesive for animal use		<u>Regulated</u>	5/23/2012
68	29/Misc/3/201 2-DC(59)	M/s. Delhi Ey Zone Pvt. Ltd., D-114, (G.F.), Lajpat Nagar-I, New Delhi-110024	1. Ophthalmic Infusion/Aspiration Cannulas	Used for injection/aspiration of fluid of gas during eye surgery	<u>Regulated</u>	5/30/2012
69	29/Misc/3/201 2-DC(62)	M/s. Pall India Pvt. Ltd., Sumer Plaza, CTS 419, Marol Maroshi Road, Andheri (East), Mumbai- 400059	1. Platelet Therapy Kit use with autologous animal blood	Intended for the preparation of a platelet concentrate form canine whole blood (C-PET) or equine whole blood (E-PET)	<u>Regulated</u>	5/30/2012

70	29/Misc/3/201 2-DC(69)	M/s. Quantum Biological Pvt. Ltd., Block-A, 36/37, Shrivasan Nagar Main Road, Perungudi, Chennai-600096	1. Vaccum Blood collection tubes without needle	Used for routine collection of venous blood	<u>Regulated</u>	6/12/2013
71	29/Misc/3/201 2-DC(68)	M/s. Corions India Private Limited, No. 5, Sri Krishna Nagar Annexe, Maaduravoyal, Chennai- 600095	1. Orthopaedics External Fixation Products	Used in infected non-unions of fractures which needs correction and for the bone deformities and bone lengthening procedures	<u>Not Regulated</u>	6/12/2013
72	29/Misc/3/201 2-DC(77)	M/s. Juno Pharma, 3rd Floor, Harith Arcade, D. No. 3- 100/2/B, Survey No. 277, Nizampet Road, Hyderabad-500090	1. Co- Flex Unna Boot Kit with calamine and cohesive bandage	Designed to treat venous leg ulcers, and diabetics foot ulcer, traumatic wounds, chronic wounds, pressure ulcer etc	<u>Regulated</u>	6/12/2012
73	29/Misc/3/201 2-DC(74)	M/s. Juno Pharma, 3rd Floor, Harith Arcade, D. No. 3- 100/2/B, Survey No. 277, Nizampet Road, Hyderabad-500090	1. T- Ring Digital Tourniquet	Used for wound exploration for foreign bodies	<u>Not Regulated</u>	6/12/2012
74	29/Misc/3/201 2-DC(72)	M/s. Juno Pharma, 3rd Floor, Harith Arcade, D. No. 3- 100/2/B, Survey No. 277, Nizampet Road, Hyderabad-500090	1. Manta Forensics sexual assault Kits (Easi Swab Store)	Used for collection of genital and oral swabs from sexual assault victim's body parts	<u>Not Regulated</u>	6/12/2012
75	29/Misc/3/201 2-DC(82)	M/s. Innvolution Med Systems, 109-110, First Floor, Roots Tower, Laxmi Nagar, District Center, New Delhi-110092	1. Yelloport Plus Laproscopic Port System		<u>Not Regulated</u>	6/12/2012
76	29/Misc/3/201 2-DC(79)	M/s. Maxlige, New No. 56, Old No. 45/62, 2nd Main, Gabbvipuram Extension, Bangalore- 560019	1. Tubing Set for Hemodialysis		<u>Regulated</u>	6/12/2012
77	29/Misc/3/201 2-DC(103)	M/s. Kanam Latex Industries Private Limited, Oppoottil Building, K.K. Road, Kottayam-686001	1. Surgical Sterile Gloves/ Non Sterile Surgical Gloves		<u>Not Regulated</u>	7/4/2012
78	29/Misc/3/201 2-DC(71)	M/s. Juno Pharma, 3rd Floor, Harith Arcade, D. No. 3- 100/2/B, Survey No. 277, Nizampet Road, Hyderabad-500090	1. Allay Menstrual Pain Patches	Use for relief of menstrual pain	<u>Regulated</u>	7/4/2012

79	29/Misc/3/201 2-DC(73)	M/s. Juno Pharma, 3rd Floor, Harith Arcade, D. No. 3- 100/2/B, Survey No. 277, Nizampet Road, Hyderabad-500090	1. Manta Forensics - DNA Profilling Kits consists of Adhesive bandages and Alcohol Pad	Used for taking DNA samples	<u>Regulated</u>	7/4/2012
80	29/Misc/3/201 2-DC(92)	M/s. Greiner Bio - One (India) Pvt. Ltd., The corenthum, 2111, Tower-A, Plot No. A/41, Sector 692, Noida-201301	1. Vacuum Blood Collection System (Vacuumised Blood Collection Tube, Multisample Needle, Tube Holder)	Tub Holder and Vacuum bube are	<u>Not Regulated</u>	7/11/2012
				Multi sample Needle (Disposable)	<u>Regulated</u>	
81	29/Misc/3/201 2-DC(99)	M/s. Metacure Limited, 22, Victoria Street, Hamilton HM 12, Bermuda	1. Optimizer III A Cardiac Contractility modulation system		<u>Not Regulated</u>	7/11/2012
82	29/Misc/3/201 2-DC(93)	M/s. Metacure Limited, 22, Victoria Street, Hamilton HM 12, Bermuda	1. Diamond (Tantalus) System		<u>Not Regulated</u>	7/11/2012
83	29/Misc/3/201 2-DC(80)	M/s. B. Braun Medical Indian Pvt. Ltd., II Floor, 23-A, Shivji Marg, Najafgarh Road, New Delhi-110015	1. Ecoflec Connect		<u>Not Regulated</u>	7/11/2012
84	29/Misc/3/201 2-DC(88)	M/s. Adroit Biomed Ltd, 2nd Floor, A-Wing, Balsmruti, Murar Road, Mulund (W), Mumbai-400080	1. respiR8 Monitor		<u>Not Regulated</u>	7/11/2012
85	29/Misc/3/201 2-DC(63)	M/s. Dentsply India Pvt. Ltd., 121 & 128, Tower A, A-41, 2nd Floor, The Corenthum, Sec-62, Noida-201301	1. Dental Gutta Percha Points	Use to fill the root canal of a tooth	<u>Not Regulated</u>	7/11/2012
86	29/Misc/3/201 1-DC(98)	M/s. Harsoria Healthcare Pvt. Ltd., 110-111, Phase IV, Udyog Vihar, Gurgaon, Haryana-122015	1. Pressure Monitoring Line		<u>Regulated</u>	7/11/2012
87	29/Misc/4/201 2-DC(41)	M/s. Becton Dickinson India Pvt. Ltd., 5th & 6th Floor, Singnature Tower B, South City I, Guragaon-122001, Haryana	1. Research use only (ROU)		<u>Not Regulated</u>	7/11/2012
88	29/Misc/3/201 2-DC(102)	M/s. Allwin Lifecare, 4, Damji Shamji Ind., Complex Off, M.C. Road, Andheri (East), Mumbai-400 093	1. Blood Line Tubing		<u>Regulated</u>	7/11/2012
89	29/Misc/3/201 2-DC(78)	M/s. Totipotent Scientific Product Pvt. Ltd., 857, Udyog Vihar, Phase-V, Gurgoan-122016	1. Umbilical Cord Tissue Transport Tube	Used for transport	<u>Not Regulated</u>	7/11/2012
90	29/Misc/3/201 2-DC(66)	M/s. Neo Medisurge, M-210, 3rd Floor, Street No. 13, Shastri Nagar, New Delhi-110034	1. Endoscopy accessories- guidewire, papillotomes, stone extension balloon, stone extraction basket, lithotripter, Polypectomy snare		<u>Regulated</u>	7/11/2012
91	29/Misc/3/201 2-DC(87)	M/s. Fresenius Medical Care India Pvt. Ltd., 11th Floor, Front Wing, Gopal Dass Bhawan, 28, Barakhamba Road, New Delhi-110001	1. Puristeril 340 & Citrasteril are disinfectants	Use for the disinfection of Hemodialysis machine	<u>Regulated</u>	7/11/2013

92	29/Misc/3/201 1-DC(90)	M/s. BL Lifesciences Pvt. Ltd., A-245, Okhla Industrial Area, Phase-I, New Delhi-110020	1. Pressure Monitoring line and Pressure Monitoring Kits		<u>Regulated</u>	7/11/2012
			2. Cardioplegia, vessel loop, toruniquet kit and Mister Blower		<u>Not Regulated</u>	7/11/2012
93	29/Misc/3/201 2-DC(70)	M/s. Wipro GE Healthcare, No. 4, Kadugodi Industrial Area, Bangalore-560067	1. IV Fluid/Blood Warming system	Enflow warmer and the enflow controller- Used to generated temperature	<u>Not Regulated</u>	7/16/2012
				Enflow disposable cartridge with or without extension set- used to connects to the IV Extension Set or any infusion set	<u>Regulated</u>	7/16/2012
94	29/Misc/3/201 2-DC(75)	M/s. Juno Pharma, 3rd Floor, Harith Arcade, D. No. 3- 100/2/B, Survey No. 277, Nizampet Road, Hyderabad-500090	1. Co-Flex (Bandage)	Used for hoding IV's and tubes	<u>Not Regulated</u>	7/16/2012
95	29/Misc/3/201 2-DC(84)	M/s. Johnson & Johnson Ltd, 30, Forjett Street, Mumbai-400036	1. Inroducer Sheath	only to protect and ensure smooth passage of coils	<u>Not Regulated</u>	7/20/2012
96	31-81- MD/2006-DC (Re-Reg 2009)	M/s. Cochlear Medical Device Company India Pvt. Ltd., Ground Floor, Platina Builidng, Plot No. C 59, G Block, Bandra Kurla Complex, Mumbai-400051	1. CP802 sound processor		<u>Not Regulated</u>	7/31/2012
97	29/Misc/3/201 2-DC(96)	M/s. Edvego Technologies, No. 41, 2nd Floor, 14th Cross, 18th Main, Padmanabha Nagar, Bangalore-560070	1. Tubing set for Hemodialysis		<u>Regulated</u>	8/1/2012
98	29/Misc/3/201 2-DC(110)	M/s. Stericat Gutstrings (P) Ltd. 169, Sector-4, IMT Manesar, Gurgaon, Haryan-122050	1. Non sterile Sutute Thread		<u>Regulated</u>	8/1/2012
99	29/Misc/3/201 2-DC(113)	M/s. Multi Meidcs, Plot No. 28, HPSIDC Phase 3, Baddi, Distt. Solan-173205 (H.P)	1. Medical device (Bare Metal Stent)		<u>Regulated</u>	8/8/2012
100	29/Misc/3/201 2-DC(129)	M/s. Zenotech Laboratories Ltd, Survey No. 250-252, Turkapally Village, Shameerpet Mandal RR Disrict 500078 A.P India	1. Htpak® Barrels (without needles), Plunger rod and Stoppers		<u>Not Regulated</u>	9/3/2012

101	29/Misc/3/201 2-DC(116)	M/s. Clairvoyance Consulting, Flat No. 801, 8th Floor, Indra Prakash Building, 21 Barakhamba Road, New Delhi-110001	1. Mefix 2. Tubifast 3. Tubigrip 4. Brevet	1.Used for fixation of catheter 2. Used for holding dressing securely in place without the need of tapes 3. Used for pressure dressing 4. Used for prevent the formation of Deep Vein Thrombosis (DVT)	<u>Not Regulated</u>	9/7/2012
102	29/Misc/3/201 2-DC(123)	M/s. Canary Impex, 221, 2nd Floor, Rajhans Shopping Center, Nr. Baroda Pristage, Vrachha Road, Surat-06	1. Disposable Hemorrhoids Stapler		<u>Regulated</u>	9/7/2012
103	29/Misc/3/201 2-DC(120)	M/s. Semler Research Center Privated Limited, 75A, 15tH Cross, I Phase, J.P Nagar, Bangalore-78	1. Magnetic Resonance- Guide High Intensity Focused Ultrasound for Pallition of painful Skeletal Metastases	Used in MR System Provide images to plan the therapy and to guide and monitor the thermal ablation with termal imaging during the treatment	<u>Not Regulated</u>	9/7/2012

104	29/Misc/3/202-DC(118)	M/s. L & T Integrated Engineering Services, Larsen & Toubro limited, Bellary Road, Byatarayanapura, Bangalore-560092	1. Clotalyst Kit with GPS III Separatory System	Is a blood fractioning Devices System, Used in prepration of autologous serum that is to be mixed with auto-graft or allograft for bone graft handling prior to the application to the orthopaedic surigcal site and the kit contains the components like- Syringes, Needle and Needle set, Tourniquet, alcohol swab pad, Tube, Bottle of ACD-A	<u>Regulated</u>	9/7/2012
105	29/Misc/3/2012-DC(130)	M/s. Emcure Pharmaceuticals Limited T-184, M.I.D.C, Bhosari, Pune- 4110026	1. Hypak® Barrels (without needlse), plunger rod and Stoppers		<u>Not Regulated</u>	9/7/2012
106	29/Misc/3/2012-DC(126)	M/s. Genova Biopharmaceuticals Limited T-184, M.I.D.C, Bhosari, Pune-411026	1. Hypak® Barrels (without needlse), plunger rod and Stoppers		<u>Not Regulated</u>	9/7/2012
107	29/Misc/3/2012-DC(124)	M/s. Global Prosumers Associates, Flat No. 11, Navbharat Appartment, 7/137, Swarup Nagar, Kanpur-208 002	1. Quantum Resonance Magnetic Analyzer (QRA)	To collect the weak magnetic field of human cells for scientific analysis	<u>Not Regulated</u>	9/7/2012
108	29/Misc/3/2012-DC(81)	M/s. S.M Health Care Products Pvt. Ltd., 14/95, 1st Floor, Geeta Colony, Delhi-110031	1. Semi-finsihed, Non Sterile Products-Catheters/ and sizes, Biopsy products/ Needlses in different types, Guide-wire and Packaging Components in different shapes and sizes, Tubing and Tubing Contractor and accessories in different materials and sizes etc		<u>Not Regulated</u>	9/7/2012
109	29/Misc/4/2012-DC(58)	M/s. Totipotent Scientific Product Pvt. Ltd., 857, Udyog Vihar, Phase-V, Gurgoan-122016	1. Umbilical Cord Tissue Transport Tube (Tube with buffered saline only no umblical cord)		<u>Not Regulated</u>	9/25/2012
110	29/Misc/3/202-DC(38)	M/s. Advance Hydrau, Components Pvt. Ltd., Khasra No. 86/24, Hiran Kundna More, Near Ganga International School, Ghevra, New Delhi-110041	1. Bandages- Soft-1 & UNI Bandaes	Used for the stop the bleeding & also to protect the wounds.	<u>Regulated</u>	9/25/2012

111	29/Misc/3/201 2-DC(128)	M/s. Neutron Sugicals Pvt. Ltd. 306, Yusug Bldg, 50/51, V. Nariman Road, Near Akbarally's Fort, Mumbai-4000001	1. Ostomy Bags	For collection of wastes form sugical diverted biological system (Colon, ileum, urinary) and certain of stoma	<u>Not Regulated</u>	9/19/2012
112	29/Misc/3/201 2-DC(115)	M/s. India Medtronic Pvt. Ltd., A-16, Mohan Co-operative Industiral Estate Ltd, Ground Floor, Mathura Road, New Delhi-110044	1. Centrifugal Blood Pump		<u>Not Regulated</u>	9/19/2012
			2. Oxygenator		<u>Not Regulated</u>	
113	29/Misc/3/201 2-DC(119)	M/s. Envy International Private Limited, NH-2, 2nd Floor, C-Block, Community Centre, Naraina Vihar, New Delhi-110028	1. Collagen Based Medifil granules & Skin temp Sheets		<u>Regulated</u>	9/19/2012
114	29/Misc/3/201 2-DC(132)	M/s. Cyro Healhcare Pvt. Ltd., C-6, Greater Kailash-1, New Delhi-110002	1. NUV ADERM Liquid Bandage 2. NUV AVET Animal Healthcare Liquid Bandage	1. Use to cover intact skin or minor cuts, scrapes, burns and irritations of the skin, to help keep them clean and dry and help to protect them from injection 2. Used on small and large animals, includidng dogs, cats, horses, hotspots, burns or other irritations of the skin to help keep then clean and dry, and help protect them form infection	<u>Regulated</u>	11/23/2012
115	29/Misc/3/201 2-DC(144)	M/s. Schulke India Pvt. Ltd., A-24/9, Mohan Co-operative Ind. Est. Mathura Road, New Delhi-110044	1. GIGAZYME	Cleaner for manual and automatic cleaning or Endoscopes and Sugical instruments.	<u>Not Regulated</u>	12/11/2012

116	29/Misc/3/201 2-DC(147)	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, Near Picket, Secunderabad- 500009 (A.P)	1. Vedera KXS System	Which delivers a short burst energy in a predetermined pattern onto human cornea	<u>Not Regulated</u>	12/11/2012
117	29/Misc/3/201 2-DC(85)	M/s. Accredited Consultants Pvt. Ltd., D-29, First Floor, Acharya Niketan, Mayor Vihar Phase-1, Delhi-110091	1. Ostomy Bags	For collection of wastes form sugical diverted biological system (Colon, ileum, urinary) and certain of stoma	<u>Not Regulated</u>	12/11/2012
118	29/Misc/3/201 2-DC(108)	M/s. Lifewatch Technologies Ltd., 2 Perkeris St. P.O. Box-527, Rehovot-76100, Israel	1. Lifewatch V		<u>Not Regulated</u>	12/13/2012
			2. Glucose test strips		<u>Regulated</u>	
119	29/Misc/3/201 2-DC(152)	M/s. BioAide Technologies Pvt. Ltd., Flat No. 207, 2nd Floor, Savitri Cinema Complex, Greater Kailash Part-11, New Delhi-110048	1. Debrisoft	Used for debridgement of acute or chronic wounds of all origin	<u>Regulated</u>	12/13/2012
120	29/Misc/3/201 2-DC(149)	M/s. Care Group India, A Unit of Polymer Technologies INTL, Block no 310 Village Sim of Dabhasa, Ta Padra, Dist Vadodara-391440	1. Corneal inlay (having no power)	Used for improving the depth of Focus by cutting the unnecessary light entering in the eye	<u>Not Regulated</u>	12/13/2012
121	29/Misc/3/201 2-DC(167)	M/s. Cambindia Biotech Kits (Pvt.) Ltd., Ground Floor, H. No. 817(A), Gurukripa Nagar, Post. Saravali, Kon Village, Tal Bhiwandi, Dist Thane Tal Bhiwand (Thane Zoens) 421311	1. Evacuated Blood Collection Container/ Tubes	Used to collect, Store, Transport and process the blood to laboratories for blood testing (investigation)	<u>Not Regulated</u>	12/31/2012

2013 Database

S. NO.	File . No.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	29/Misc/3/2012-DC(175)	M/s. Labtech Disposables 406-Shefali Shopping Centre, Paldi Char Rasta, Ahmedabad-6	1. Blood Collection Tubes		<u>Not Regulated</u>	1/3/2013
2	29/Misc/3/2012-DC(154)	M/s. Imacor Inc, 839, Stewart avenue Suite 3, Garden City, NY 11530-4863	1. ImaCor Zura™ Imaging System and ImaCor Zura- Evo™ Imaging System With Claritee Probe		<u>Not Regulated</u>	1/8/2013
3	29/Misc/3/2012-DC(50)	M/s. Bear Medic Corporation, Yushima 2-31-24, Bunkyo-Ku, Tokyo 113-0034 Japan	1. Disposable Micro Vascular Clip		<u>Not Regulated</u>	1/8/2013
4	29/Misc/3/2012-DC(158)	M/s. T Bose, Col Dir AFMS (Prov) Post Contract Management Cell, Raksha Mantrayala, Karyala Mahinideshak, Sashastra Sena Chikitsa Sewa, M Block New Delhi-110001	1. Endo Path Tristar Surgical Trocar 5 MM and 10/11 with Safety Shield		<u>Not Regulated</u>	1/8/2013
5	29/Misc/3/2012-DC(76)	M/s. Juno Pharma, 3rd Floor, Haritha Arcade, D. No. 3-100/2/B, Survey No. 277, Nizampet Road, Hyderabad-500090	1. Manta Forensics Unidentified		<u>Not Regulated</u>	1/8/2013
6	29/Misc/3/2012-DC(151)	M/s. Chadha & Co., Advocates & Legal Consultants, S-327, Greater Kailash-II, New Delhi-110048	1. Prevena™ Incision Management System		<u>Regulated</u>	2/19/2013
7	29/Misc/3/2013-DC(08)	M/s. Teriage Healthcare Technologies Flat No.. 17, Aashirwad Apartments, Property No. 886-C/8, Mehrauli, New Delhi-110030	1. Comprehensive Negative Pressure Wound Therapy Dressing Pack		<u>Regulated</u>	2/19/2013
8	29/Misc/3/2013-DC(15)	M/s. Cambindia Biotech Kits (Pvt.) Ltd., A-208, Partik Industrial Estate, Mulund-Goregoan Lind Road, Mulund(W) Mumbai-400078, Maharashtra	1. Luer Adaptor		<u>Regulated</u>	2/26/2013
9	29/Misc/3/2013-DC(16)	M/s. Emergo (India) Consulting Pvt. Ltd., 8/1, Vasavi Colony, Kaka Guda, Secunderabad, Andhra Pradesh-500009	1. Pharmajet Startis Needle free injection System		<u>Not Regulated</u>	2/26/2013
10	29/Misc/3/2013-DC(25)	M/s. Gambro India Pvt. Ltd., No. 5, Sixth Floor, Crown Court No. 34/New no. 128, Cathedral Road Chennai-600086	1. Oxiris Set		<u>Regulated</u>	3/6/2013
11	29/Misc/3/2013-DC(23)	M/s. Bombay Dental & Surgical Pvt. Ltd., D-104/105, Sitladevi C.H.S Ltd, D.N Nagar, Opp Indian Oil Nagar, New Link Road, Andheri (W), Mumbai-400043	1. Surface Cleaner & Intermediate Level Disinfectant		<u>Regulated</u>	3/6/2013

12	29/Misc/3/2013-DC(18)	M/s. Stryker Indai Pvt. Ltd., C-5, SDA, Commercial Complex New Delhi-110016	1. Transcend Guidewires		<u>Regulated</u>	3/6/2013
13	29/Misc/3/2013-DC(21)	M/s. Bell Surigcal, Unit No. 68, Part A, Municipal Industrial Estate, Gandhi Nagar, Worli, Mumbai-400018	1. Casting Tape intended to fix broken or dislocated bone		<u>Regulated</u>	3/6/2013
14	29/Misc/3/2013-DC(26)	M/s. Covidien Healthcare India Pvt. Ltd., 10th Floor, Building No. 9 B, DLF Cyber City, Phase-3, Gurgaon-122002, Haryana	1. MyOcclude		<u>Not Regulated</u>	4/2/2013
15	29/Misc/3/2013-DC(34)	M/s. Abbott Healthcare Pvt. Ltd., 4, Corporate Park, Sion Trombay Road, Mumbai-400071, India	1. Acetium Capsule		<u>Regulated</u>	4/5/2013
16	29/Misc/3/2012-DC(188)	M/s. Anamed Instruments Pvt. Ltd., P.O. Box No: 8336, Ujagar Industrial Estate, W.T.P. Road, Deonar, Mumbai-400088	1. Intracranial Pressure (ICP) monitoring and drainage system		<u>Regulated</u>	4/5/2013
17	29/Misc/3/2013-DC(11)	Dr. A B Bhamare, Dy. Dean (CPD) Municipal Corporation of Greater Mumbai, Central Purchase Department, Medicine Tender Section, 566, N.M. Joshi Marg, Byculla, Mumbai-110002	1. Sutures		<u>Not Regulated</u>	4/5/2013
18	29/Misc/3/2013-DC(17)	M/s. Delhi Eye Zone Pvt. Ltd., D-114, G.F, Lajpat Nagar-1, New Delhi-110024	1. Tiggerfish (the Sensor)		<u>Not Regulated</u>	4/9/2013
19	29/Misc/3/2013-DC(52)	M/s. Allied Healthcare India 3, Arumugam Street, Anna Salai, Chennai-600002	1. Enteral Feeding set for giving nutrition for patients		<u>Regulated</u>	4/9/2013
20	29/Misc/3/2013-DC(36)	M/s. Eli Lily and Company (India) Pvt. Ltd., Plot No. 92, Sector-32, Gurgaon-122001 Haryana	1. HumaPen Savvio pen Injector		<u>Not Regulated</u>	4/23/2013
21	29/Misc/3/2013-DC(10)	M/s. Sterile Medical Apps. Inc., A-140/1, Okhla Industrial Area, Phase-II, New Delhi-20	1. Surgical Dressing		<u>Regulated</u>	4/23/2013
22	29/Misc/3/2013-DC(58)	M/s. Bappa Morya Enterprises, 4, Ganga Joyti C.H.S, Bangur Nagar, Goregaon (W), Mumbai-400090	1. Breastlight (Blood vessels in breast)		<u>Not Regulated</u>	4/23/2013
23	29/Misc/3/2012-DC(01)	M/s. Guerbet India Liaison Office 422, Level 4, Augusta Point Sector 53, Golf Course Road, Gurgaon-122002	1. Lipiodal		<u>Regulated</u>	4/23/2013
24	29/Misc/3/2013-DC(53)	M/s. Emergo (India) Consulting Pvt. Ltd., 8/1, Vasavi Colony, kaka Guda, Secunderabad, Andhra Pradesh-500009	1. Gutta Percha		<u>Not Regulated</u>	4/29/2013
25	29/Misc/3/2013-DC(62)	M/s. Litejoy International Private Limited, S-289, Ground Floor, Greater Kailash-I, New Delhi-110048	1. Disposable Electronic Cigarettes		<u>Not Regulated</u>	4/30/2013
26	29/Misc/3/2013-DC(60)	M/s. Intas Medi Devices Limited, 9th Floor, Premier House-1, S.G Highway, Bodakdev Ahmedabad-380054	1. Guidewires		<u>Regulated</u>	4/30/2013
27	29/Misc/3/2013-DC(28)	M/s. Ecobase, Lieserhoferstraße 7-9851. Lieserbrucka Austria	1. Activated Zeolite		<u>Regulated</u>	4/30/2013
28	29/Misc/3/2013-DC(55)	M/s. GlaxoSmithKline Asia Pvt. Ltd., Plot No. 67, Sector-32, Gurgaon-122001, Hayana	1. Denture Cleansing Cream		<u>Not Regulated</u>	4/30/2013
29	29/Misc/3/2013-DC(55)	M/s. GlaxoSmithKline Asia Pvt. Ltd., Plot No. 67, Sector-32, Gurgaon-122001, Hayana	1. Denture Cleansing Tablets		<u>Regulated</u>	4/30/2013
30	29/Misc/3/2013-DC(64)	M/s. Terra India, 5/20, Punjabi Bagh Extn. New Delhi-110026	1. Health Worker Bag and Vacuum Extractor		<u>Regulated</u>	5/1/2013

31	29/Misc/3/2013-DC(57)	Shri A. Ranga Rao, Principal Co-Ordinator (ASHA), H. No. 8-2-595/2/B, Road No. 10, Banjara Hills, Hyderabad-500034, Andhra Pradesh	1. Re-Usage of Singale Use Devices (SUD)	Not Regulated	5/1/2013
32	29/Misc/3/2013-DC(54)	M/s. India Medtronic Pvt. Ltd., A-16, Mohan Co-operative Industrial Estate Ltd., Ground Floor, Mathura Road, New Delhi-110044	1. Merocel Hemox Sponges	Regulated	5/8/2013
33	29/Misc/3/2013-DC(50)	M/s. Meril Endosurgery Pvt. Ltd., Survey No. 135/2/B, Bilakhia House Muktanand Marg, Chala, Vapi-396191, Gujarat	1. Cartridge/Pins	Regulated	5/9/2013
34	29/Misc/3/2013-DC(50)	M/s. Meril Endosurgery Pvt. Ltd., Survey No. 135/2/B, Bilakhia House Muktanand Marg, Chala, Vapi-396191, Gujarat	1. Staplers (Instrument)	Not Regulated	5/9/2013
35	29/Misc/3/2012-DC(166)	M/s. Sibre Systems and Services Pvt. Ltd., 2E/12, 4th Floor, Jhandewalan Extn. New Delhi-110055	1. SB Knife (Monopolar ESD knife) 2. Flexible overtube (Guide tube for passing the pharynx)	Regulated	5/9/2013
36	29/Misc/3/2012-DC(166)	M/s. Sibre Systems and Services Pvt. Ltd., 2E/12, 4th Floor, Jhandewalan Extn. New Delhi-110055	1. Tentacles 2. SB Disposable Hood for ESD Products	Not Regulated	5/9/2013
37	29/Misc/3/2013-DC(68)	M/s. Vipros Lifesciences, 402-403, Sarthik-II, Oppt. Rajpath Club, S.G Road, Ahmedabad	1. Condoms	Regulated	5/21/2013
38	29/Misc/3/2013-DC(39)	M/s. Stryker Indai Pvt. Ltd., C-5, SDA, Commercial Complex New Delhi-110016	1. Trevo Retrievers	Regulated	5/21/2013
39	29/Misc/3/2013-DC(74)	M/s. Vinvish Technologies Pvt. Ltd., C-16, Level C, Thejaswini Building, Technopark, Trivandrum, Kerala-695581	1. Photo Dynamic Therapy Laser system	Not Regulated	5/21/2013
40	29/Misc/3/2013-DC(75)	M/s. Zest Othocare Pvt. Ltd., 48, 1st Floor, Sardar Nagar Society, Sumul Diary Road, Surat-395008	1. CAST O LITE	Regulated	6/3/2013
41	29/Misc/3/2012-DC(170)	M/s. Taneermedico A/S DTU Sciences Park, Agern Alle 3, DK-2970 Horsholm, Denmark	1. Asonor	Regulated	6/4/2013
42	29/Misc/3/2012-DC(173)	M/s. Safetec Healthcare and Hygiene Pvt. Ltd., Block No. 1, Plot No. A-13, Chakan MIDC, Phase-IV, Village-Nighoje, Tal: Khed, Dist-Pune-410501	1. Disinfectants	Regulated	6/4/2013
43	29/Misc/3/2013-DC(138)	M/s. Intech Safety Pvt. Ltd., 83 & 84 Chanditala Main Road, Kolkata-700053	1. Self Generating Oxygen Type Chemical Self Rescuer (SCSR)	Regulated	6/4/2013
44	29/Misc/3/2013-DC(05)	M/s. South India Surgical Co. Ltd., #117/65, Wallajah Road, Chennai-600002	1. Capsule Endoscope	Not Regulated	6/4/2013
45	29/Misc/3/2012-DC(153)	M/s. B. Braun Medical (India) Pvt. Ltd., III Floor, 23-A, Shivaji Marg, Najafgarh Road New Delhi-110015	1. Sol-Cart B	Regulated	6/4/2013
46	29/Misc/3/2012-DC(117)	M/s. Emergo (India) Consulting Pvt. Ltd., 8/1, Vasavi Colony, kaka Guda, Secunderabad, Andhra Pradesh-500009	1. Mix2Vial Transfer Devices	Regulated	6/4/2013
47	29/Misc/3/2012-DC(176)	M/s. Kamuk Life, 01 Darshan Enclave, Bopal-Ghuma Road, Ghuma-380058	1. Magical Granule Patch	Not Regulated	6/11/2013
48	29/Misc/3/2012-DC(85)	M/s. Silverline Worldwide Logistics Rex Chamber, Office No. 310/311, 3rd Floor, Walchand Hirachand Marg, Near Jahaz Bhavan, Ballard Estate, Mumabai-400001	1. Othopedi Casting Tapes	Regulated	6/14/2013

49	29/Misc/3/2012-DC(92)	M/s. Greatlinx Impex Pvt. Ltd., 104, Vanchinad Building, Kaloor, Cochin, Kerala, 682017	1. Silicone Gel Ointment and Silicone Sheet		Regulated	6/18/2013
50	29/Misc/3/2013-DC(89)	M/s. Benson Medical Equipments (India) Pvt. Ltd., New Delhi	1. Medical Equipment's		Not Regulated	7/3/2013
51	29/Misc/3/2013-DC(101)	M/s. Q Pharm Cousulting India # 26, Hi-Rise Colony, Phase-II, Nizampet, Hyderabad-500090	1. Personal Lubricant, "PROBE"		Regulated	7/9/2013
52	29/Misc/3/2012-DC(172)	M/s. HLL Lifecare Limited, A Govt of India Enterprises, HLL Bhavan, Poojappura, Thiruvananthapuram-695012	1. Empty PVC Bags		Not Regulated	7/9/2013
53	29/Misc/3/2012-DC(97)	M/s. Gambro India Pvt. Ltd., No. 5, Sixth Floor, Crown Court No. 34/New no. 128, Cathedral Road Chennai-600086	1. Bicart		Regulated	7/15/2013
54	29/Misc/3/2013-DC(110)	M/s. Orchid India Medisolutions Private Limited, Flat No. 305, 3rd Floor, Shroff Soleno Solitair, Surey No. 12/2/1 & 12/2/2, Mhalunge, Pune-411045	1. Othopedic Implants		Regulated	7/19/2013
55	29/Misc/3/2013-DC(48)	M/s. Nextgen Solution Pvt. Ltd., E-501, Sunflower Society, Gundecha Colony, Thakur Village, Kandivali (E), Mumbai-400101	1. Double Pump RF Day Cassette & Double Pump RF Patients Cassette		Not Regulated	7/19/2013
56	29/Misc/3/2013-DC(111)	M/s. Sterimed Inc., Peringannur, Peringode, Pattambi-679535 Palakkad, Kerela, India	1. Sterilization monitoring		Not Regulated	7/23/2013
57	12-01/13-DC (Pt-35)	Mr. Manish Agarwal, Lt. Col, JDMS (Procurement) Integrated HQ of MOD (Army), Adjunct Gernal's Branch, Dte. Gen. of Medical Services (Army) 'L' Block, New Delhi	1. Haemostatic Bandages/Gauze with Chitosan		Regulated	8/6/2013
58	29/Misc/3/2012-DC(141)	Mr. Pramod Kumar, Foreign Trade Development Officer, Ministry of Commerce and Industry, Directorate Gernal of Foreign Trade Udyog Bhawan, New Delhi	1. Rehabilitation Aids (Back Supports, Cervical Aids, Cervical Pillows, Wrist and Elbow Support, Weight Cuff, Orthopaedic Stockinette, Knee Calf Supports, Ankle Othosis, Fracture Aids, Pelvic Traction Kit		Not Regulated	8/6/2013
59	29/Misc/3/2013-DC(65)	M/s. Star Radiance Medical Devices Training Aids No. 5&6, G-2, Crystal Glade, Kothandan Street, Devendran Nagar, Kundrathur, Chennai-600059	1. Indigo Carmine		Regulated	8/6/2013
60	29/Misc/3/2013-DC(59)	M/s. India Medtronic Pvt. Ltd., A-16, Mohan Co-operative Industrial Estate Ltd., Ground Floor, Mathura Road, New Delhi-110044	1. Heart Positioners (Starfish and Urchin), Centrifugal Blood Pump (Bio-Pump), Arterial Filters (Affinity Arterial Filters), Cardioplegia Delivery System (Myotherm XP) and Tissue Stabilizer (Octopus)		Not Regulated	8/6/2013
61	29/Misc/3/2012-DC(91)	M/s. Kimberly-Clark Hygiene Products Pvt. Ltd., Survey No. 279, Raisoni Industrial Park, Village Mann, Taluka, Mulshi, Pune-411057	1. Kim Vent Yankuer 2. Kim Vent Suction Handle 3. Kim Vent Oral Care Suction Tooth Brush		Not Regulated	8/6/2013
62	29/Misc/3/2013-DC(87)	M/s. Covidien Healthcare India Pvt. Ltd., 10th Floor, Building No. 9 B, DLF Cyber City, Phase-3, Gurgaon-122002, Haryana	1. Surgisleeve		Not Regulated	8/6/2013

63	29/Misc/3/2013-DC(116)	M/s. Becton Dickinson India Pvt. Ltd., 5th Floor, Signature Tower B, South City I, Gurgaon-12201, Haryana, India	1. BD Sentry Safety Lancet		Regulated	8/5/2013
64	29/Misc/3/2013-DC(127)	M/s. India Sani Chem C-28, Pushpanjali Farms, Bijwasan, New Delhi-110061	1. Echo-Clean PRO Purge		Not Regulated	8/12/2013
65	29/Misc/3/2013-DC(132)	M/s. Mtex India Private Limited A-26/4, Mohan Co-operative Industrial Estate, Mathura Road, New Delhi-110044	1. X Cura Cast 2. X Cura Splint		Regulated	8/27/2013
66	29/Misc/3/2013-DC(75)	M/s. Zest Othocare Pvt. Ltd., 48, 1st Floor, Sardar Nagar Society, Sumul Diary Road, Surat-395008	1. ALTOCAST		Regulated	9/3/2013
67	29/Misc/3/2013-DC(133)	M/s. Susruta Instruments Pvt. Ltd., Plot No. 87/3/B-1, First Floor, Opp. Pushpak Estate, Phase 1, G.I.D.C. Vatva, Ahmedabad-382445	1.. Ophthalmic, ENT, Dental Microsurgical Blades and Knives, Ophthalmic Instruments Including Probes, Forceps, Scissors, Speculum, Needle Holder and Ophthalmic		Not Regulated	9/3/2013
68	29/Misc/3/2013-DC(29)	M/s. Becton Dickinson India Pvt. Ltd., 5th Floor, Signature Tower B, South City I, Gurgaon-12201, Haryana, India	1. BD Phaseal (Closed System Drug Transfer Device)		Regulated	9/4/2013
69	29/Misc/3/2013-DC(93)	M/s. Meril Endosurgery Pvt. Ltd., Survey No. 135/2/B, Bilakhia House Muktanand Marg, Chala, Vapi-396191, Gujarat	1. Surgical Trocar		Not Regulated	9/4/2013
70	29/Misc/3/2013-DC(113)	M/s. Nanz Med Sciences Pharma (P) Ltd., Rampur Ghat, Paonta Sahib, District Sirmour, H.P	1. Isopropyl Alcohol/Pre Injection Swabs	Use for personal hand hygien to help or prevent the	Regulated	9/10/2013
71	29/Misc/3/2013-DC(138)	M/s. Rekha Production Pvt. Ltd., & SGS Sciences, Aditya Enclave, Flat #G11, Kanchna Junga 'D' Block, Ameerpet, Hyderabad.	1. Anti-radiation Chip		Not Regulated	9/10/2013
72	29/Misc/3/2013-DC(142)	Sh. Sudhir Kumar, Under Secretary (Drugs), (DFQC Section), Ministry of Health & Family Welfare, Nirman Bhavan, New Delhi-110108	1. X-Ray equipment/ X-Ray (S)		Not Regulated	9/25/2013
73	29/Misc/3/2013-DC(136)	M/s. Faith Innovation, E-107, Lajpat Nagar-I, New Delhi-110024	1. Sterigen Disinfectant Generation System Super Oxidized solution/Sterigen solution containing salts like Sodium Hypochlorite, Hypochlorous acid, Hygreogen peroxide, Ozone, Chlorine dioxide, Sodium Hydroxide, Sodium Carbonate and Sodium Chloride	Used as a disinfectant	Regulated	10/14/2013
74	29/Misc/3/2013-DC(69)	M/s. Chitrarath, 5 Darshana Bhawan, HR/62A, Sohan Lal Marg, Pul Pahladpur, New Delhi-110044	1. Sureseal (Self activatin Pressure Bandage)		Regulated	10/21/2013

75	29/Misc/3/2013-DC(107)	M/s. 3M India Ltd., Plot No. 48-51, Electronics City, Hosur Road, Bangalore-560100	1.Ceramic/Metallic Brackets 2.Buccal Tubes 3. Archwire Products 4. Bonding/Banding Products 5. Curing Light 6. Intraoral Product 7. Extraoral Products 8. Instruments.	1. Correction of misaligned crooked teeth 2.For the molar teeth, to support the movement of the front teeth 3. Used to move the teeth along with the brackets and in some cases elastics 4. Used to stick the bracket or band to the surface of the tooth temporarily, till the teeth are removed 5. To cure or	<u>Not Regulated</u>	10/21/2013
76	29/Misc/3/2013-DC(127)	M/s. Ivoclar Vivadent Marketing (India) Private Limited, 503-504 Raheja Plaza, 15B, Shah Industrial Estate, Off Veera Deasi Road, Andheri (w), Mumbai-400053	1. Dental Consumables	Cervitec liquid and Gel, a ready to use antibacterial mouth rinse inhibiting	<u>Regulated</u>	10/22/2013
77	29/Misc/3/2013-DC(156)	M/s. Pushpanjali Medi India Pvt. Ltd., Gandhi House, 16, Ganesh Chandra Avenue, 5th Floor, Kolkata-700013	1. Cerederm Silicone Dressing	Intended for preventive treatment	<u>Regulated</u>	10/22/2013
78	29/Misc/3/2013-DC(154)	M/s. PAT Pharma Consultant Consultant Pvt. Ltd., Unit No. IInd Floor, Vikas Surya Arcade, Plot No. 7, CU Block, Pitampura, Delhi-110088	1. Endostim Lower Esophagal Sphincter Stimulation System		<u>Not Regulated</u>	11/12/2013
79	29/Misc/3/2013-DC(152)	M/s. CellBios Healthcare and Life Sciences Pvt. Ltd., 1/7, First Floor, Poonamallee High Road, Vanagaram, Chennai 600095, Tamilnadu	1. Freezing Bags Transfer Set	Intended for stroage of Peripheral Blood	<u>Regulated</u>	11/19/2013
80	29/Misc/3/2013-DC(150)	M/s. Incredible Group C.O.: 909 Kedar Building, Clock Tower, Delhi-110007	1. NUTAS E-10(Non-Invasive Ultrasound Tumor Ablations System)	is Medical equipment which utilizes high intensity focused	<u>Not Regulated</u>	11/19/2013
81	29/Misc/3/2013-DC(125)	M/s. Hospital Equipment Manufacturing Company D-313, Sector-63, Noida, Distt. Gautam Budh Nagar, Uttar Pradesh 201301	1. Laryngoscope Blades and Handles 2. Resuscitator	1. Intended to obtain the view of the vocal folds and glottis 2. A device used	<u>Not Regulated</u>	11/26/2013

82	29/Misc/3/2013-DC(112)	M/s. 3M India Ltd., Plot No. 48-51, Electroics City, Hosur Road, Bangalore-560100	1. IV Securement Dressings		<u>Regulated</u>	11/26/2013
83	29/Misc/3/2013-DC(167)	Mr. Om Prakash, Section officer, Govt of India, Ministry of Health & Family Welfare DFQC Section, Nirman Bhawan, New Delhi	1. AERB (Medical X-ray equipment under subheading of Exim code-9022		<u>Not Regulated</u>	11/26/2013
84	29/Misc/3/2012-DC(143)	M/s. Emergo (India) Consulting Pvt. Ltd., 8/1, Vasavi Colony, kaka Guda, Secunderabad, Andhra Pradesh-500009	1. Atricure Cry Module System & Articure Abalation System		<u>Not Regulated</u>	12/6/2013
85	29/Misc/3/2013-DC(176)	M/s. Med Evolution Devices Pvt. Ltd., New No. 7, Old No. 4, I Cross Steet, Shastri Nagar, Adyar, Chennai-600020	1. Bone Marrow Biopsy Needles 2. Soft Tissue Biopsy Needles 3. Cytohistological Biopsy Needles		<u>Regulated</u>	12/11/2013
86	29/Misc/3/2013-DC(183)	M/s. M.J. Medical Devices Private Limited, 706, Rajgir Sadan, 7th Floor, Lami Baug, Mumbai-400022	1. Flexiseq	Treatment of pain associated with	<u>Regulated</u>	12/16/2013
87	29/Misc/3/2013-DC(171)	M/s. Beiersdorf India Pvt. Ltd., Niranchal Road, Curti, Ponda, Goa 403409	1. Kid Plaster	For the Protection of minor cuts and abrasion on the skin	<u>Regulated</u>	12/27/2013
88	29/Misc/3/2013-DC(175)	M/s. Molnlyke Healthcare Inida Pvt. Ltd.,C-1664, AKD Tower, Sushant Lok-1, Guragaon	1. Mepore IV	For fixation of intravascular devices such as IV Catheters, Peripheral	<u>Not Regulated</u>	12/27/2013
89	29/Misc/3/2013-DC(174)	M/s. OnMed India Pvt. Ltd., 425/22, Shasi-Neel Apt. 7-8, T.M.V. Colony Gultekdi, Pune 411037	1. Sennex Electro-Chemotherapy Unit	Used to deliver chemotherapy ot cancer tumors by quick pulsating	<u>Not Regulated</u>	12/27/2013

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S. NO.	File . No.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	29/Misc/3/2013-DC(177)	M/s. DHR Holding India Pvt. Ltd., Plot NO. 121, Phase IV, Udyog Vihar, Gurgaon 122002	1. HemoCue Cleaners	Use for cleaning the cover glasses of the optronic Unit for HemoCure photometers and analyzers	Not Regulated	1/3/2014
2	29/Misc/3/2013-DC(163)	M/s. Smith & Nephew Healthcare Pvt. Ltd., B-508, 509, Dynasty Business Park, Andheri-Kurla Road, Andheri (E), Mumbai 400059	1. External Fixation Systems	Taylor Spatial Frame and JET-X Extrenal Fixator, and external method of skeletal Immobilization	Not Regulated	1/15/2014
3	3(M/D)/2013-DC(116)	M/s. Becton Dickinson India Pvt. Ltd., No. 34 Assisi Nagar, West Thottam, Madhavram, Chennai 51	1. BD Vacutainer Blood Transfer Device (without needle)		Not Regulated	1/15/2014
4	29/Misc/3/2013-DC(181)	M/s. Coloplast (India) Pvt. Ltd., Khasra Nos 44/14/2, 17 & 47/4,5,6,7 Village-Taj Nagar, Patudi Road, District-Gurgaon	1. Coloplast Paste & Brava Strip Paste	A periwound dressing intended for filling in cavities/folds in the skin around the stoma and protecting skin against stoma output	Regulated	1/15/2014
5	29/Misc/3/2013-DC(164)	M/s. Coloplast (India) Pvt. Ltd., Khasra Nos 44/14/2, 17 & 47/4,5,6,7 Village-Taj Nagar, Patudi Road, District-Gurgaon	1. Comfeel Cleanser 2. Brava Protective Sheet	1. Intended for cleansing of skin exposed to urine, faeces, urine and pus and in removing skin barriers. 2. Intended for protection of skin against stoma output, and for skin protection.	Regulated	1/15/2014
6	29/Misc/3/2013-DC(187)	M/s. Occu'passion Retails Pvt. Ltd., 1-106, Road No. 3, Himgiri Enclave, Chander Vihar, Nilothi Extension, New Delhi-41	1. EPI-Mini- Mobile ECG Monitoring Device	Which enables individuals to instaneously record their heart rhythm measurement (ECG) at a touch of their fingers with clinical precision providing remote health monitoring solution	Not Regulated	1/15/2014
7	29/Misc/3/2013-DC(189)	M/s. Sken Healthcare Pvt. Ltd., B-1001, Growmore Towers, Plot No. 5, Sector-2, Kharghar, Navi Mumbai, Maharashtra 410210	1. Natalis Birth Gel	Consisting of 1 sterile disposable syringe each containing 15 ml Birth gel individually packed in sterile packaging with vaginal catheter intended for easing vaginal birth	Regulated	1/15/2014
8	29/Misc/3/2013-DC(108)	M/s. Terra India, 5/20, Punjabi Bagh Extn., New Delhi 110026	1. Cold Box 2. Mannual Ventose(Vaccum Extractor) 3. Mask 4. Oxygen Flow Regulator 5. Vaccination Carrier 6. Comkunity Health Worker Kit		Not Regulated	1/15/2014
9	29/Misc/3/2013-DC(172)	M/s. Progen SAA Technologies India (P) Ltd. 809, Eighth Floor, Tower-I Pearls Omaxe, Netaji Subhash Place, Pitampura, New Delhi 110034	1. Disinfectants (Antiseptica Combi Instrument-N & Triacid-N	Use for disinfection of instruments & laboratory equipment	Regulated	1/20/2014
10	29/Misc/3/2013-DC(155)	M/s. Gnana Medical Private Limited, Old No. 16, Defence Colony, Edaduthangal, Chennai-097, Tamil Nadu	1. Gnana Laryngeal Airway	Use for Cardiopulmonary resuscitation and during surgery to allow anesthetic gases and oxygen to enter into a patients lung	Regulated	1/21/2014

11	29/Misc/3/2013-DC(130)	M/s. India Medtronic Pvt. Ltd., 4-16 Mohan Co-operative Industrial Estate Ltd., Ground Floor, Mathura Road, New Delhi-110044	1. Ambulatory Insulin Infusion Pump Reservoir 2. Disposable Infusion Sets for Ambulatory Pumps 3. Ambulatory Insulin Infusion pumps	Use for the subcutaneous infusion of medication, including insulin from an infusion pump	<u>Regulated</u>	1/21/2014
12	29/Misc/3/2013-DC(169)	M/s. Molnlycke Health Care India Private Limitd C-1664, AKD, Tower, Sushant Lok-I, Gurgaon	1. Barrier Surgical Drapes (Sterile)	1. Intended to provide optimal barrier against microbial migration and effective infection control	<u>Regulated</u>	1/21/2014
			2. Barrier Surgical Staff Clothing, 3. Barrier Supplementaries (Stand Covers, Table Covers, Pouches, Equipment Drapes) 4. Barrier Easywarm Blanket		<u>Not Regulated</u>	
13	29/Misc/3/2013-DC(147)	M/s. Eucare Pharmaceuticals Private Limited, Plot No. AC-25B, SIDCO Industrial Estate, Thirumudivakkam, Chennai 600044	1. EUCAPS Concentrated Autologous Platelet System	Use for separation platelets from autologous whole blood is available as a kit consisting of Hypodermic syringe coated with ADP, three way stop cock, filters, saline solution etc	<u>Regulated</u>	1/21/2014
14	29/Misc/3/2014-DC(05)	M/s. Group Pharmaceuticals Ltd., Devraj Bldg, A Wing 4th Floor, S.V. Road, Goregan, Mumbai 400062	1. BioFilm, Mouth Ulcer Dissolvable Strips	BioFilm, a mouth Ulcer Dissolvable Strip intended for topical application to areas of the mucosal surface affected by minor aphthous ulcers, oral abrasions or cuts	<u>Regulated</u>	1/28/2014
15	29/Misc/3/2014-DC(06)	M/s. Pushpanjali Medi India Pvt. Ltd., Gandhi House, 16, Ganesh Chandra Avenue, 5th Floor, Kolkata 700013	1. Glustitch-Twist Topical Tissue Adhesive	Use the topical closure of surgical skin incisions and trauma induced laceration in areas of low skin tension uncomplicated skin lacerations where there is little or no tissue loss.	<u>Regulated</u>	1/28/2014
16	29/Misc/3/2014-DC(04)	M/s. Sharma Dental Supply Co. Newal Kishore Road, Hazratganj, Lucknow 226001	1. CollaPlug-C, Hemostatic Collagen Sponge	Use as Hemostatic Agent	<u>Regulated</u>	1/28/2014
17	29/Misc/3/2014-DC(09)	M/s. ISCON Surgicals Ltd., B-70, Marundhar Industrial Area, Phase-II, Bansi, Jodhpur, Rajashtan-342005	1. Bone Marrow Biospy Needle- Unsterile Bulk		<u>Regulated</u>	2/25/2014
18	29/Misc/3/2013-DC(151)	M/s. Virdis BioPharma Pvt. Ltd., 6/10 Jogani Industrial Complex, V.N. Purav Marg, Chunabhatti, Mumbai 400022	1. Dental Sealant		<u>Regulated</u>	2/25/2014
19	29/Misc/3/2014-DC(12)	M/s. Surgimedik Healthcare, 1B-904, Green Acres, Lokhandwala Complex, Andher (W), Mumbai-400053	1. Dexell	Use for Vesicoureteral Reflux (VUR)	<u>Regulated</u>	3/7/2014
20	29/Misc/3/2014-DC(24)	M/s. Deputy Drugs Controller (I), CDSCO (South Zone) 2nd Floor, Shastri Bhawan Annexe 26, Haddow Road, Chennai-06	1. Negative Pressure Wound Therapy Machine		<u>Not Regulated</u>	4/23/2014
21	29/Misc/3/2014-DC(21)	M/s. Clairvoyance Consulting, Flat No. 801, 8th Floor, Indra Prakash Building, 21 Barakhamba Road, New Delhi-110001	1. TorqMax	Use in providing grip on outer support sheaths, dilator sheaths and spectranetics laser sheaths	<u>Not Regulated</u>	4/30/2014

22	29/Misc/3/2014-DC(23)	M/s. Surgimedik Healthcare India Pvt. Ltd., Surgimedik House, 53 CD, Kandivali Co-operative Industrial Estate, Charkop, Kankivali West, Mumbai-40067	1. Guidewires		Regulated	4/30/2014
23	29/Misc/3/2014-DC(10)	M/s. Wellness Concepts, 10, Om Appartments, Sundervan Complex, Near Sab TV, Andheri (W), Mumbai-400053	1. FitNes	Use as an adjunctive therapy for reducing the frequency of seizure in patients who are refractory to antiepileptic medications	Not Regulated	4/30/2014
24	29/Misc/3/2014-DC(07)	M/s. Genesee Criticare Device Pvt. Ltd., 303, Aggarwal Complex, Block A-1, LSC, Janakpuri, New Delhi-110058	1. The Tandem Heart System	Use for the temporary circulatory support as Ventricular Assist device by optimal unloading of ventricle to recover from cardiogenic shock	Regulated	5/2/2014
25	29/Misc/3/2013-DC(28)	Dr. V. Bhujanga Rao, 29, DRDO Bhawan, Rajaji Marg, New Delhi-110011	1. Cochlear Implant	By this directorate under the category of Internal Prothetic Replacement	Regulated	5/5/2014
26	29/Misc/3/2014-DC(31)	M/s. Nanz Med Scinces Pharma (P)Ltd., Rampur Ghat, Paonta Sahib, District Sirmour, H.P	1. Isopropyl Alcohol/ Pre Injection Swabs		Regulated	5/6/2014
27	29/Misc/3/2014-DC(19)	M/s. Terumo Penpol Ltd., Deviprabha, T.C 9/1330(15) Kattachal Bhagavathy Lane, Sasthamangalam, Thiruvananthapuram-695010	1. Mirasol Platelet Disposabale Kits for Tretment in Plasma 2. Mirasol DOUBLE + Platelet Disposable Kit for Treatment in plasma 3. Mirasol Platelet Disposable Kit for treatment in Platement Additive Solution 4.Mirasol DOUBLE + Platelet Disposable Kit for treatment in Platelet Additive Solution	Use for the treatment in plasma/ platelet additive solution	Regulated	5/6/2014
28	29/Misc/3/2013-DC(179)	M/s. India Medtronic Pvt. Ltd., 4-16 Mohan Co-operative Industrial Estate Ltd., Ground Floor, Mathura Road, New Delhi-110044	1. Deep Brain Stimulation Kit, Spinal Cord Stimulation Kit, Intersim Test Stimulation Kit	Intended to deliver electrical stimulation to selected areas of the brain, spinal cord or peripheral nervous systems	Not Regulated	5/15/2014
29	29/Misc/3/2013-DC(26)	Prof. N. Khandelwal President, Indian Society of Vascular & Interventional Radiology Department of Neuroradiology, CN Centre, Room No. 15, AIIMS, Ansari Nagar, New Delhi-110029	1. Polyvinyl Alcohol Foam (PVA)		Regulated	5/21/2014
30	29/Misc/3/2014-DC(39)	M/s. Abbott Healthcare Pvt. Ltd., Corporate Park Sion Trpmbay Road, Mumbai-400071	1. OROSOL spray	Intended as an adjuant in the management of chemo & radio thery including oral mucositis or ulcer of the oral mucosa alongwith standard treatment	Regulated	5/30/2014
31	29/Misc/3/2014-DC(34)	M/s. Surgiplus, Plot No. 2, 5th Cross, Gnanaprakasam Nagar, Pondicherry-605008	1. Scalp Vein Infusion Sets 2. Extension Tube 3. 3 Way stopcock 4. Disposable Syringe		Regulated	6/4/2014

32	29/Misc/3/2014-DC(22)	M/s. Terumo Penpol Ltd., Deviprabha, T.C 9/1330(15) Kattachal Bhagavathy Lane, Sasthamangalam, Thiruvananthapuram-695010	1. Spectra Optia Exchange set 2. Cobe Spectra Product 3. Trima Accel Product		<u>Regulated</u>	6/4/2014
33	29/Misc/3/2014-DC(48)	Mr. S S Bhatia Col, Dy. Commandant, Armed Forces Medical Stores Depot, Delhi Cantt-10	1. Ligating Clips		<u>Regulated</u>	6/6/2014
34	29/Misc/3/2014-DC(42)	M/s. Medilinks Inc., 03, Noble House, Gr. Flr, Dr. Batliawala Labe Parel, Mumbai-400012	1. External Breast Prosthesis Maxima		<u>Not Regulated</u>	6/9/2014
35	29/Misc/3/2013-DC(190)	M/s. Earthrays Pvt. Ltd., 48 Qutab View Apts., Shaheed Jeet Singh Marg, New Delhi-110016	1. BEMER (Sets, PRO & Classic)	Use to support the body's fundamental physiological process, thereby promoting the improvement of natural self regulatory mechanism on microcirculations, immune system, protein synthesis	<u>Not Regulated</u>	6/9/2014
36	29/Misc/3/2014-DC(17)	M/s. Win Medicare Private Ltd., 1400, Modi Tower, 98 Nehru Place, New Delhi-110019, India	1. Contractubex OIP (Overnight Intensive Patches) Transdermal Patches		<u>Regulated</u>	6/25/2014
37	29/Misc/3/2014-DC(50)	Mr. Samir Mehta, Bio-Medical Engineer, C-150, Oshiwara Industrial Centre, Opp. Oshiwara Bus Depot, New Link Road, Goregaon (west) Mumbai-400104	1. Esophagel Stent & Biliary Stent		<u>Regulated</u>	7/4/2014

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S. NO.	File . No.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	29/Misc./3/2014-DC (207)	M/s. Nirma Limited, Nirma House, Ashram Road, Ahmedabad-380009 Gujarat	Duragraft-Vascular Conduit Storage Solution	For the preservation, Storage and flushing of vascular conduits prior to grafting in vascular surgeries	Not Regulated	01.01.2015
2	29/Misc./3/2014-DC (176)	M/s. Biomet Orthopaedic India Pvt. Ltd., office no. - 811, Building No. 08, Solitaire Corporation Park, Andheri Ghatkopar Link Road, Chakala, Andheri East, Mumbai - 400093	Abutments " Internal Prosthetic Replacements"		Regulated	01.01.2015
3	29/Misc./3/2014-DC (97)	M/s. Phoenix Cardio Care India Pvt. Ltd., 53, Syed Amir Ali Avenue, 3rd Floor, Suite-3B, Kolkata-700019	Inflation Device	Consisting of Syringe, tubing etc. intended to be used in the intervention operation which is to be connected with balloon catheter and could supply liquor pressure to make the balloon catheter inflating and deflating	Regulated	01.01.2015
4	29/Misc./3/2014-DC (146)	M/s. Vigen Healthy Tech India Pvt. Ltd., Plot no. 16-17, Near Brahma Apartment Sector-7, Dwarka, new Delhi - 110075	"TOP 8500-Special"	For body massage	Not Regulated	05.01.2015
5	29/Misc./3/2014-DC (161)	M/s. Neurosynaptic Communications Pvt. Ltd., #10, 29th Main, BTM Layout II Stage, Bangalore-560076	Tele-Medicine Solution ReMeDi (Remote Medical Diagnostics, which is Telemedicine Solution)	Its components which measure basic physiological parameters and provide information about the patient health	Not Regulated	15.01.2015
6	29/Misc./3/2014-DC (150)	M/s. Serum Institute of India Ltd., 212/2 Hadaspar, Pune-411028	Stratis Needle Free Injector System	Use auto-disable needle-free jet injector intended to deliver the fluid volumes either intramuscularly (IM) or subcutaneously (SC) by means of high-velocity fluid jet & "stratis reset station" used to prepare (set) the injector spring for an injection	Not Regulated	19.01.2015
7	29/Misc./3/2014-DC (188)	M/s. Nutri Synapzz Therapeutics Pvt. Ltd., No. 203, 2nd Floor, BEML 4th stage, Rajarajeswari Nagar, Bangalore-560098	EZ Partum Obstetric Gel (EZ Partum)	Highly bioadhesive and has a high water-binding capacity. This product is used during natural delivery to make the birth easier for both mother and child and to protect the perineum. It has no pharmacological activity.	Not Regulated	21.01.2015

8	29/Misc./3/2014-DC (192)	M/s. Zywie Medical Devices Pvt. Ltd., # Manjeera Majestic Commercial, JNTU-Hitech City Road, Kukatpally, Hyderabad-500085, Telegana, India	Pressure Right	Pressure Right non-drug, externally applied, disposable, single use P6 acupressure, adhesive wrist strip to be applied on both wrist during use: indicated for the relief of emetic (nausea and vomiting) symptoms.	Not Regulated	28.01.2015
9	29/Misc./3/2014-DC (205)	M/s. Orbit Lifesciences Pvt. Ltd., Gala No. 1, Building No. G, Ground Floor, Phase-II, Munisurat complex, Survey No. 122, Village Rehnal, Bhiwandi Dist. Thane, Tal: Bhiwandi (Thane-Zone5) Pin:421302	EdgeFile Heat Treated Firewire NiTi Reciprocating Files	EdgeFile Heat Treated Firewire NiTi Reciprocating Files is an instrument indicated for the removal of dentin and root canal shaping.	Not Regulated	30.01.2015
10	29/Misc./3/2014-DC (33)	M/s. J Mitra & Bros., P.O.Box : 2809, 20 Double Storey Market, New Rajinder Nagar, New Delhi-110060	HeartWare Ventricular Assist System		Not Regulated	03.02.2015
11	29/Misc./3/2014-DC (163)	M/s. Well-Tech Imports and Exports (P) Ltd., B4 & B5, Jeevarathinam Maaligai, No. 25, Arcot Road, Vellore-632004, Tamil Nadu, India	O2 VIGOR PORTABLE CANNED OXYGEN	O2 VIGOR PORTABLE CANNED OXYGEN is considered under "Medical Oxygen" as specified in India Pharmacopoeia (IP) 2014 "Drug"	Regulated	05.02.2015
12	29/Misc./3/2014-DC (51)	M/s. Duraant Biologicals Ltd., 1-98/9/12A, 2nd Floor, Jain Enclave, T & A Plaza, madhapur, hyderabad 500081	Perfadex	For flushing, storage and transportation of isolated lungs after removal from the donor in preparation for external transplantation into a recipient	Not Regulated	05.02.2015
13	29/Misc./3/2014-DC (124)	M/s. Chitrarth, 5, Dasshan bhawan, hr/62A, Sohan Lal marg, pul pahladpur, new delhi - 110044	Sureseal XL - self activating pressure dressing		Regulated	11.02.2015
14	29/Misc./3/2015-DC (02)	M/s. Galderma India Pvt. Ltd., Lotus Corporate Park, D Wing Unit 801 & 802, Graham Firth Steel Compound, Western Express Highways, Goregaon Tal: Goregaon (East), Mumbai	Pix L® and PixL® + Cannulas	Pix' L® (Pix' L® 27 G, Pix'L® 25G, Pix'L® 23G) and Pix'L® + (Pix' L® +28G, Pix'L® + 25G) are needles & cannulas for single use sterile for dermal, subcutaneous and supraperiosteal deposits of hyaluronic acid for facial tissue augmentation.	Regulated	11.02.2015
15	29/Misc./3/2015-DC (14)	M/s. Novateur Electrical & Digital Systems Pvt. Ltd., 61/62, 6th Floor, Kalparatu Square, Kondivita Road, Off Andheri kurla road andheri (e), mumbai - 400059	Blood pressure cuffs, stethoscope, probes, thermometer, telemedicine portable health monitor, etc.		Not Regulated	11.02.2015
16	29/Misc./3/2015-DC (17)	M/s. Piramal enterprises limited, 320 tower-B, DLF Towers, jasola, new delhi 110025	radiopharmaceutical product " Neuraceq™ (Florbetaben F18 injection)	Neuraceq™ (florbetaben F18 injection) is a radiopharmaceutical product meant for early diagnosis of Alzheimer's disease	Regulated	19.02.2015

17	29/Misc./3/2015-DC (4)	M/s. South India Surgical Co. Ltd., 177/65, Wallajah road , chennai - 600002	OMT spetzler Neuro patties	OMT spetzler Neuro patties" are non-absorbent surgical sponges intended ofr control of hemorrhage and protection of tissues weaves & delicate structures during surgery as well as for absorption & drying of corporal fluid that limits the vision of the surgical field during procedure. (Surgical Dressing)	Regulated	09.03.2015
18	29/Misc./3/2015-DC (30)	M/s. Mtex India Pvt. Ltd., a-26/4, mohan c0-operative industrial estate, mathura road, new delhi-110044	Synthetic casting Tape	synthetic casting tape 'consist of knitted fiberglass (polyester) fabric impregnated with polyurethane resin when exposed to moisture of water initiate a chemical reacton which cause tape to become rigid.	Regulated	09.03.2015
19	29/Misc./3/2015-DC (09)	M/s. Timpac Healthcare Pvt. Ltd., -169, Naraina Industrial Area, Phase-I, New Delhi-110028	Density PRP Test Tubes with separating Gelx2	Density PRP Test Tubes with separating Gelx2" the tubes with anticoagulant such as Sodium Floride Gel etc., used ofr the purpose of collecting and transporting blood samples for testing at clinical laboratories/Centrifugatuon.	Regulated	10.03.2015
20	29/Misc./3/2015-DC (19)	M/s. Sun Pharmaceutical Industries Ltd., tandalja vadodara - 390020	Starhaler Device	Starhaler Device" which is meant to collect user's respiratory flow profile data	Not Regulated	10.03.2015
21	29/Misc./3/2015-DC (40)	M/s. Motivation India, No.1436 Ground Floor, BTS Depot , Hennur Main Road Bangalore-560043	Wheelchair trials	Development & testing of an affordable tilt in space peditric wheelchair for less resource setting.	Not Regulated	10.03.2015
22	29/Misc./3/2015-DC (144)	M/s. Meril Life Sciences pvt. Ltd. Survey no. 135/2/A, near g m bilakhia stadium muktanand marg chala vapi - 396191	Merigraft pericardium covered stent graft system.	product for examination, testing and analysis .	Regulated	26.03.2015
23	29/Misc./3/2015-DC (44)	M/s. Tara Lohia Distributors, 24, Sri ram road , civil lines, delhi - 110054	Smart breathe	Smart Breathe' smart breathe is a device interded to increase the oxygen supply to the cells increasing the immine system stronge and increasing protection of the body from viruses, microbes, parasites etc.	Not Regulated	26.03.2015
24	29/Misc./3/2015-DC (57)	M/s. Paviour pharmaceuticals pvt. Ltd., 311-312 suneja tower-1, distt centre, janak puri, new delhi-110058	caphosol	caphosol' with the composition of dibasic sodium phosphate 0.032 % w/w, monobasic sodium phosphate 0.009 % w/w, calcium chloride 0.052 % w/w, Sodium Chloride 0.569 % w/w) which is also indicated as "an adjunct to standard oral care In the prevention and treatment of the mcositis that may be cased by radiation or high doe chemotherapy.	Regulated	27.03.2015

25	29/Misc./3/2015-DC (145)	M/s. Meril Life Sciences pvt. Ltd. Survey no. 135/2/A, near g m bilakhia stadium muktanand marg chala vapi - 396191	Chronic Occlusion (CTO) Device	Chronic Occlusion (CTO) Device a single use, disposable, sterile catheter for the purpose of examination, test or analysis only at M/s. Merillife sciences pvt. Ltd.	Regulated	27.03.2015
26	29/Misc./3/2015-DC (142)	M/s. Meril Life Sciences pvt. Ltd. Survey no. 135/2/A, near g m bilakhia stadium muktanand marg chala vapi - 396191	Intracoronary Shunt	a sterile, single use disposable shunt composed of two bulbs on the distal ends of a flexible shaft for the purpose of examination, test or analysis only M/s. Meril Life sciences pvt. Ltd., survey 135/2/A, near g m bilakhia stadium, muktanand marg, chala, vapi 396191	Regulated	27.03.2015
27	29/Misc./3/2015-DC (58)	M/s. Meril Endosurgery Pvt. Ltd., Survey no. 135/2/A, near g m bilakhia stadium muktanand marg chala vapi - 396191	Bone Wax	Bone wax which is indicated to aid in the control of bleeding in bone injuries is regulated as surgical products	Regulated	27.03.2015
28	29/Misc./3/2015-DC (42)	M/s. Siro Clinpharm Pvt. Ltd., DIL Premises, 2nd Floor, Swami Vivekanand Road, Near Tatwagyan Vidyapeeth, Ghodbunder Road, Thane (west) - 400610	SpO2 sensors and pulse oximeter monitors	SpO2 sensors and pulse oximeter monitors : (a) Nellcor N600x Pulse Oximeter monitors (b) Low Acuity Multi-parameter (LAMP) family of monitors (c) Masimo Radical-87 monitors	Not Regulated	30.03.2015
29	29/Misc./3/2015-DC (140)	M/s. Meril Life Sciences pvt. Ltd. Survey no. 135/2/A, near g m bilakhia stadium muktanand marg chala vapi - 396191	Fractional Flow Reserve (FFR) Pressure Guidewire	Fractional Flow Reserve (FFR) Pressure Guidewire is a steerable guidewire with a ultra micron pressure sensor die mounted 30 mm from the radiopaque tip of the guidewire for the purpose of examination, test of analysis only at M/s. Meril Life Sciences pvt. Ltd. Survey no. 135/2/A, near g m bilakhia stadium muktanand marg chala vapi - 396191	for test NOC	01.04.2015
30	29/Misc./3/2015-DC (47)	M/s. Accredited Consultants Pvt. Ltd., D-29, First Floor, Acharya Niketan, Mayur Vihar - 1, Delhi - 110091	Swabable Vial Adapter	Swabable Vial Adapter is a transfer device intended for safe and easy transfer of liquid drug from & into vial as a part of or through syringes before administration to the patients.	Regulated	21.04.2015
31	29/Misc./3/2015-DC (46)	M/s. Kentron Biotechnology Pvt. Ltd., No.8, 1st Floor, 1st Block, 15th Cross, R.T. Nagar, Bangalore-560032	a) Transurethral Microwave Therapy Device b) Prolieve System Treatment Catheter	a) intended for the treatment of symptomatic Benign Prostatic Hyperplasia in men b) used in the device	a) not regulated b) Regulated	21.04.2015
32	29/Misc./3/2015-DC (73)	M/s. Paul Hartmann Medical Pvt. Ltd., B/506, 5th Floor, Titanium Square, Thalje, Ahmedabad - 380059, Gujarat	Hydroclean Plus, Hydrotac, Zetuvit, Zetuvit Plus, Permafoam, Cosmopore IV, Hydrofilm IV, Hydrofilm IV control and Peha-haft LF	these products are wound dressing products used in healing of wound and management	Regulated	29.04.2015

33	29/Misc./3/2015-DC (81)	M/s. Merz India Healthcare Pvt. Ltd., Level 3, Office No. 337, Neo Vikram, Above audi show room, New Link Road, Andheri (W), Mumbai -400053	Ulthera System	use as a non-invasive dermatological aesthetic treatment to lift eyebrow, lax submental and neck tissue	Not Regulated	29.04.2015
34	29/Misc./3/2015-DC (74)	m/s. Fresenius kabi India Pvt. Ltd., Registered office & factory, A-3, MIDC, Ranjangaon Ganpati, Tal: Shirur, Dist. Pune-412220	Freedlex Transfer Adapter	indicated to drug transfer from Vials to Freeflex in close system	regulated	29.04.2015
35	29/Misc./3/2015-DC (77)	M/s. Elite Jair Studio Pvt. Ltd., 1-11-252/12, Motilal Nehru Nagar, Begumpet, Hyderabad, India	Hair Max Laser Comp Advances 7, hair Max Laser Comb Lux 9 and Hair Max Laser Comb Professional 12	intended to treat androgenetic alopecia and promote hair growth	Not Regulated	29.04.2015
36	29/Misc./3/2015-DC (82)	M/s. CliniExperts Service Pvt. Ltd., 112, 113, 114, C-58, Shahpuri Tower, Janakpuri, New Delhi - 110058	Zip 8i surgical skin closure device and Zip 16 surgical skin closure device	indicted for non-invasive surgical skin closure	Regulated	29.04.2015
37	29/Misc./3/2015-DC (66)	M/s. Becton Dickinson India Pvt. Ltd., 5th & 6th Floor, Signature Tower-B, South City-1, Gurgaon-122001	BD Uniject™ DP Prefillable Delivery System	is a container closure system for packing and installation of vaccines and potentially oral drugs	Not Regulated	29.04.2015
38	29/Misc./3/2015-DC (07)	M/s. India Medtronic Pvt. Ltd., 1241, Solitaire Corporate Park, building Number 12, 4th Floor, Andheri-Ghatkopar Link Road, Andheri (E), Mumbai - 400093, Maharashtra	The Pillar System- Palatal Implants	consisting of a delivery tool and an implant i.e. 14 Gauge needle intended for use in stiffening the soft palate tissue as such the said product	Regulated	30.04.2015
39	29/Misc./3/2015-DC (130)	M/s. LifeCell International Pvt. Ltd., #26, Vandalur Kelambakkam Main Road, Keelakottaiyur, Chennai-600127	Umbilical Cord Blood Collection Kit Boxes	intended to facilitate sterile collection of cord blood and tissue	for export NOC	30.04.2015
40	29/Misc./3/2015-DC (72)	M/s. Observe Design Pvt. Ltd., Level-3, C-28, Malviya Nagar, New Delhi-110017	Sakshield- Hand Sanitizer Dispenser	Hand sanitizer Dispenser (without any disinfectant or sanitizer) which dispenses hand sanitizer using a mechanical or an electronic mechanism	Not Regulated	05.05.2015
41	29/Misc./3/2015-DC (75)	M/s. KOB Medical Textiles Pvt. Ltd., No. 116, Trichy Road, Ondipudur, Coimbatore -641016, Tamilnadu	Novopress LF-T 752 and Rinkilastic Cohesive 184 LF	products are latex free elastic, non-woven, hydrophobic cohesive elastic bandage	Regulated	05.05.2015
42	29/Misc./3/2015-DC (76)	M/s. Denex International, H No. 169P, Sector 14, Huda, Gurgaon -122001	a) catheter mount b) clave connector c) connectors d) umbilical Catheter e) corrugated drain Sheet f) urine collection bag g) Mucus Extractor h) 3 - way stop cock i) Extension line j) Manifold k) closed wound drainage set (VAC Set) and l) skin stapler		Regulated	05.05.2015

43	29/Misc./3/2015-DC (76)	M/s. Denex International, H No. 169P, Sector 14, Huda, Gurgaon -122001	a) Umbilical Cord Clamp b) lung Exercizer c) Oxygen Mask d) Surgical Blades e) Blood lancets and f) Disposable Hygiene wear		Not Regulated	05.05.2015
44	29/Misc./3/2015-DC (71)	M/s. Chandra Corporation, 102, Konark Opp. Sadhanagar, nr. Chepi Rog Hospital, Vedmandir road, karelbaug, vadodara -390018	Orthopaedic Casting Tape	used to keep a broken bone in place while it heals	Regulated	05.05.2015
45	29/Misc./3/2014-DC (76)	M/s. Emergo (india) Consulting Pvt. Ltd., 8/1, First Floor, Vasavi Colony, Kakaguda, Near Picket, Secunderabad, MCH-Circle-7, mandal, Hyderabad - 500009 A.P.	β -powder - β -Tricalcium Phosphate (β TCP)	intended for cleaning and polishing patient's tooth surface by emitting the powder from an airbrush under air or water pressure	Not Regulated	07.05.2015
46	29/Misc./3/2014-DC (70)	M/s. Meril Endosurgery Pvt. Ltd., Survey no. 135/2/A, near g m bilakhia stadium muktanand marg chala vapi - 396191	Absorbable Heostat (Oxidized regenerated cellulose)	a sterile, absorbable knitted fabric used adjunctively in surgical procedures to assist in the control of capillary, veous and small arterial hemorrhage when ligation or other conventional methods of control are impractical or ineffective for the purpose of examination, test or analysis only at M/s. Meril Endosurgery Pvt. Ltd., Survey no. 135/2/A, near g m bilakhia stadium muktanand marg chala vapi - 396191	for test NOC	12.05.2015
47	29/Misc./3/2015-DC (96)	Dr. V.G. Mohan Prasad, VGM Hospital, 2100, Trichy Road, Coimbatore-641005, Tamilnadu	Endoscopic Tubes / pipes	basic endoscopic device (flexible endoscope with 3 internal lumens and around 130cm. Long tube).	Regulated	18.05.2015
48	29/Misc./3/2015-DC (100)	M/s. Shree Pacetronix Ltd., Plot No. 15, Sector II, Pithampur, dist. Dhar, Madhya Pradesh-454775	Cardiac Pacemaker		Not Regulated	18.05.2015
49	29/Misc./3/2015-DC (47)	M/s. Regulatory Solutions India, F-2/13, DLF Qutub Enclave, Phase-I, Gurgaon, haryana-122002	Minitouch Device	intended for ablation of the endometrial lining of the uterus for the tratment of menorrhagia (excessive uterine bleeding) due to benign causes in premenopausal women for whom child bearing is complete	Not Regulated	18.05.2015
50	29/Misc./3/2015-DC (118)	M/s. Johnson & Johnson Pvt. Ltd., 9/43, Kirti Nagar, New Delhi - 110015	Sterile Lancet	used to prick the skin for blood sampling	Not Regulated	20.05.2015
51	29/Misc./3/2015-DC (104)	M/s. Emcure Pharmaceuticals Limited, T-184, M.I.D.C. Bhosari, Pune-411026	Histidine-Typtophan-Ketoglutarate (HTK) Solutions	intended for flushing, storage and transportation of isolated lungs after removal from the donor in preparation for external transplantation into a recipient	Not Regulated	22.05.2015
52	29/Misc./3/2015-DC (119)	M/s. Ortho Prime, 470, Jawahar Marg Siyaganj, Indore-452007	Fiberglass Orthopedic Tape	used as a casting tape in case of treatment of fractures	Regulated	22.05.2015

53	29/Misc./3/2015-DC (80)	M/s. Scepre Medical (India) Pvt. Ltd., 14, 1st Floor, Central Market, Ashok Vihar, Phase-I, Delhi-110052	Unfinished & Unsterile Products	Unfinished & Unsterile components of catheter, guidewire, dialator, hollow syringe, introducer needle, stylet, trocar, needle wings, PVC Tube, Luer Locks/ connectors, clamp etc. for the purpose of further manufacturing like cutting, molding, assembling for finished goods	goods are not covered under the provision of drugs and cosmetics act 1940 and rules thereunder	26.05.2015
54	29/Misc./3/2015-DC (67)	Mr. mukesh Kumar, Inspector of Police, Central Bureau of Investigation, anti corruption branch, plot no. 5B, CGO Complex, Lodi Road, New Delhi-110003	Film for medical radiography		Not Regulated	02.06.2015
55	29/Misc./3/2014-DC (47)	M/s. Regulatory Solutions India, F-2/13, DLF Qutub Enclave, Phase-I, Gurgaon, haryana-122002	Minitouch Device	intended for ablation of the endometrial lining of the uterus for the tratment of menorrhagia (excessive uterine bleeding) due to benign causes in premenopausal women for whom child bearing is complete	Not Regulated	09.06.2015
56	29/Misc./3/2015-DC (136)	M/s. Durent Biologicals Ltd., 1-98/9/12A, 2nd Floor, Jain Enclave, T & A Plaza, Madhapur, Hyderabad-500081	THAM-trometamol, tris-hydroxymethyl aminomethane	intended to adust the pH to 7.4 of Perfadex® solution (used for flushing, storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient)	Not Regulated	12.06.2015
57	29/Misc./3/2013-DC (179)	M/s. India Medtronic Pvt. Ltd., A-16, Mohan Cooperative Indus Estate Ltd., Ground Floor, Mathura Road, New Delhi-110044, India	Synchromed pump without catheter		Not Regulated	16.06.2015
58	29/Misc./3/2015-DC (127)	M/s. Gel Craft Healthcare (P) Ltd., 306, Deepshikha Building, 43 veer savarkar Block, shakarpur, vikas marg, delhi-110092	C ₃ I Gel™ Technology based products		Not Regulated	16.06.2015
59	29/Misc./3/2015-DC (02)	M/s. Galderma India Pvt. Ltd., Lotus Corporate Park, D Wing Unit 801 & 802, Graham Firth Steel Compund, Western Express Highways, Goregaon Tal: Goregaon (East), Mumbai	PixL® and PixL® + cannulas	there is no provision for import of device/drug for demo purpose		19.06.2015
60	29/Misc./3/2015-DC (162)	M/s. Prowin Health Technologies Pvt. Ltd., B-18, 1st Floor, Vengalarao Nagar, Opp Post Office, S. R. Nagar, Hyderabad - 500038	Smart Coat (Nano Titanium Dioxide)	The product smart coat containsn n-type semiconductor photo-catalyst, as an active ingredien whice are nao-sized Titanium Dioxide (TiO ₂) particles. It is applied by spraying on to a designated surface, or any other such as walls, ceiling, curtains,cupboards, cushions and almost every surface including glasses which require full transparency	Not Regulated	16.06.2015
61	29/Misc./3/2015-DC (143)	M/s. Lakshmi Life Sciences Ltd., 3/284 A, Sular Railway Feeder Road, Kurumbapalayam, M.G. pudur (PO), Coimbatore-641406	1. closed suction catheter (sterile) - catheter 2. 3 way stop cock with extension (Sterile) - Disposable Perfusion Set 3. Yankur suction Set (Sterile) - catheter		Regulated	19.06.2015

62	29/Misc./3/2015-DC (88)	Mr. mukesh Kumar, Inspector of Police, Central Bureau of Investigation, anti corruption branch, plot no. 5B, CGO Complex, Lodi Road, New Delhi-110003	a). Vaccutainers fitted with needle b). Vaccutainers without Needle	a). Under the category of Disposable Hypodermic Needle which were notified vide G.S.R. 365(E) b) does not come under the preview of Drugs & Cosmetics Act	a) regulated b) not Regulated	30.06.2015
63	29/Misc./3/2015-DC (156)	M/s. Happy Medicare Pvt. Ltd., Plot No. 1, Palam Kunj, Near Ramphal Chowk, Palam Extension, Sector-7, Dwarka, New Delhi-110075	Automatic massage bed, waist belt, mint mat, cushion and single mat	not notified as medical devices under the provisions of Drugs & Cosmetics Act	Not Regulated	30.06.2015
64	29/Misc./3/2015-DC (152)	M/s. Sahaj Regenerative Cell Therapeutics LLP, 13/2, South Tukogani, Indore, madhya Pradesh	Cole-Parmer (Ultrasonic Processors)	which is an equipment for homogenisation of tissue in laboratory	Not Regulated	03.07.2015
65	29/Misc./3/2015-DC (93)	M/s. Eleven2Six Store, WZ-1367, Rani Bagh Shakur Basti, New Delhi-110034	Master-Aid Ortopad (Orthoptic Eye Patch)	indicated to act as mechanical barrier for eye treatment of strabismus (Lazy eye) and amblyopis and for campimetry	Not Regulated	07.07.2015
66	29/Misc./3/2015-DC (153)	m/s. Creative Responsible Integrated System Foundaton, Ground Floor, Madhav Baug, Brahmin Society, naupada, Thane-400602, Maharashtra	G-1 Negative Pressure Ventilator (Portable Ventilator)		Not Regulated	07.07.2015
67	29/Misc./3/2015-DC (158)	M/s. Meril Endo Surgery Pvt Ltd., Survey No. 135/2/B and 174/2, Third Floor, E1-E3, Meril park, muktanand Marg, Chala, vapi, Dist. Valsad-396191	Ligating Clips	use in surgery for vessel closer as well as for making purposes	Regulated	15.07.2015
68	29/Misc./3/2015-DC (158)	M/s. Healthy Options Pvt. Ltd., 14, Vigyan Vihar, Delhi-110092	Electric Massaging Equipment		Not Regulated	15.07.2015
69	29/Misc./3/2015-DC (155)	M/s. Amarante Wellness Zone, 14, Vigyan Vihar Sports Complex, Opp. HDFC Bank, New Delhi-110092	electric equipments viz., beauty machine, massaging machine etc.		Not Regulated	17.07.2015
70	29/Misc./3/2015-DC (150)	M/s. Wealth Taxi Technology Pvt. Ltd., 24/4818, First Floor, Prahlad Street, Ansari Road, Daryaganj, new Delhi-110002	iRemeber (A Smart Pill Organizer)		Not Regulated	17.07.2015
71	29/Misc./3/2015-DC (145)	M/s. WomenCare Global International, 160 Chesterfield Dr # 2, Cardiff, CA 922007, United states	CAYA SILCS Diaphragm	which is indicated for prevention of pregnancy is regulated as drugs under section 3, clause (b), sub clause (ii)	Regulated	21.07.2015
72	29/Misc./3/2015-DC (79)	M/s. CareFusion, 22745 Savi Ranch Parkway, Yorba Linda CA 92887-4668, USA	AVEA Ventilator care products	1. AVEA Ventilator Esophageal Pressure Monitoring tube set 2. AVEA Ventilator Extension Esophageal Pressure Monitoring tube set (Adult & Pediatric) 3. AVEA Ventilator Nasogastric pressure monitoring tube set (Adult & Pediatric) 4. AVEA Ventilator varflex/ adapter tracheal pressure monitoring tube set	Regulated	24.07.2015

73	29/Misc./3/2015-DC (160)	M/s. Schulke India Pvt. Ltd., A-24/9, Mohan Co-operative Industrial Estate, Mathura Road, New Delhi-110044	Thrmosept Xtra	which is a mildly alkaline machine detergent based on surfactants and enzymes for the universal cleaning of medical instruments and accessories is not notified as medical device	Not Regulated	24.07.2015
74	29/Misc./3/2015-DC (68)	M/s. Krupa Medix, 3/37, thirumangal Alwar Street, NH-1, Maraimalai Nagar, tamil nadu pin- 603209 M/s. Corions India Pvt. Ltd., No5, Sri Krishna Nagar Annexe, maaduravoyal, chennai-600095	Orthopaedics External Fixation Products	used in infected non-unions of fractures which need correction and for the bone deformities and bone lengthening procedures	Not Regulated	29.07.2015 12.06.2012
75	29/Misc./3/2015-DC (141)	Dr. Chetan Bhardwaj, C-15, Green Park Main, New delhi-110016	Magneto-Therapeutic Devices (ALMAG-01 & ALMAG-02)		Not Regulated	31.07.2015
76	29/Misc./3/2015-DC (110)	M/s. Chayagraphics (India) Pvt. Ltd., 248, 4th Main Road, Chamarajpet, Bangalore-560018	a) Intercept Detergent b) Rapicide OPA/28 High Level Disinfectant c) Rapicide POA/28 Test Strips	a) intended for cleaning of endoscopes, surgical instruments and accessories b) ----- c) used for the determination of Minimum Recommended Concentration (MRC) of ortho-Phthalaldehyde	a) not regulated b) Regulated c) not regulated	31.07.2015
77	29/Misc./3/2015-DC (163)	M/s. Albert David Limited, 4/11, asaf ali road, new delhi-110002	Both Sterile and Non-sterile Disposable Hypodermic Syringes and Disposable Hypodermic Needled		Regulated	03.08.2015
78	29/Misc./3/2015-DC (166)	M/s. Envision Scientific Pvt. Ltd., Shop No. 4, Silver Palm-2, Kadampalli, Nanpura, Surat-395001	Lipoid E80 (excipient)	act as a carrier for drug eluting stent systems in the coating process	Not Regulated	04.08.2015
79	29/Misc./3/2015-DC (171)	M/s. Stericate Gutstrings (P) Ltd., Plot No. 169, ,sector-4, IMT-Manesar, Gurgaon, haryana	a) Sterile Hemostatic clip made of pure Titanium grad-1 b) Hemostatic clips (Raw material in the bulk form of clip)	a) Nil b) for sterilization and packing for sale	a) regulated b) regulated	05.08.2015
80	29/Misc./3/2015-DC (175)	M/s. Dentspec, C-1987 (First Floor), Sushant Lok-1, Gurgaon -122002	Improalgin & Hydrocol (Alginate Impression Materials)	used to take dental impressions and to study models	Not Regulated	04.08.2015
81	29/Misc./3/2015-DC (177)	M/s. Aramex trading Co., 9-ashok Nagar, Lucknow, Uttar Pradesh	Fluor Gel	indicated for the prevention (Prophylaxis) of caries	Regulated	04.08.2015
82	29/Misc./3/2015-DC (173)	M/s. Aramex trading Co., 9-ashok Nagar, Lucknow, Uttar Pradesh	1. Xero Cem (Automix Eugenol-free temporary cement) Tfill Eco (Temporary filling Material) 3. Proklene (Prophylaxis Paste regular)	used for temporary filling of teeth and temporary cementing of crowns	Not Regulated	04.08.2015
83	29/Misc./3/2015-DC (174)	M/s. LifeCell International Pvt. Ltd., #26, Vandalur Kelambakkam Main Road, Keelakottaiyur, Chennai-600127	Cord collection clamp	used to collect the umbilical cord blood from umbilical cord during placental delivery of the baby	Not Regulated	12.08.2015

84	29/Misc./3/2015-DC(71)	M/s. Chandra Corporation, 102, Konark Opp. Sadhanagar, nr. Chepi Rog Hospital, Vedmandir road, karelbaug, vadodara -390018	Orthopaedic Casting Tape	used to keep a broken bone in place while it heals	Regulated	05.05.2015 12.08.2015
85	29/Misc./3/2015-DC(181)	M/s. Joseph Lesile & Co. LLP, Leslico House, 3rd Floor, Pro. V. s. Agashe Rd., Dadar-West, Mumbai-400028	Water Gel Based Blankets	used as a body wrap to extinguish fires and to cool and moisten burns	Not Regulated	25.08.2015
86	29/Misc./3/2015-DC(188)	M/s. CAmbIndia Biotech Kits Pvt. Ltd., 208, Pratik Industrial estate, Mulund-Goragaon Link Road, Next to Fortis Hospital, Mulund (west), Mumbai-400078	cApillary Collection Lancets	indicated to prick the finger for blood glucose monitoring	Not Regulated	25.08.2015
87	29/Misc./3/2015-DC(184)	M/s. Shreyas Health Care, New No. 73 (Old No. 5A), Iind Floor, Lal Bhagathur colony, Peelamedu, Coimbatore -641004	Voice Prosthesis	used by cancer surgeons after removal of larynx and creating a small surgical puncture on the throat (stoma) and placing the prosthesis in the passage for speaking	Not Regulated	31.08.2015
88	29/Misc./3/2015-DC(138)	M/s. Becton Dickinson India Pvt. Ltd., 5th & 6th Floor, Signature Tower-B, South City-1, Gurgaon-122001	BD Uniject Prefillable Injection System	supplied to pharmaceutical manufactureres as a prefillable drug container with delivery function of hypodermic needle designed with non-reusable function for the parenteral administration of drugs of vaccines either through intramuscular of sucutaneous injection	Regulated	31.08.2015
89	29/Misc./3/2015-DC(09)	M/s. Timpac Healthcare Pvt. Ltd., -169, Naraina Industrial Area, Phase-I, New Delhi-110028	Density Platelet Gel	comprising of the kit containing set of blood taking test (with needle butterfly, tourniquet, plasters) containing inert gel, syringes and pharmaceutical grade sodium citrate (ACD-A),used for the purpose of collecting and transporting blood samples for testing at clinical laboratories/centrifugation	Regulated	01.09.2015
90	29/Misc./3/2015-DC(202)	M/s. Morulaa HealthTech Pvt. Ltd., Plot. No. 38, First Floor, Rajeshwari Street, Santhosh Nagar, Kandanchavdi, Chennai-600096	The Woodpecker	indicated to be used as a rasp device for femoral broaching	Not Regulated	01.09.2015
91	29/Misc./3/2015-DC(204)	M/s. UE Marketing Pvt. Ltd., A-102, Universal Paradise, Nanda Patkar Road, Vile Parle (East), Mumbai-400057	iBrest Exam	which is a Breast lesion documentation system	Not Regulated	03.09.2015
92	29/Misc./3/2015-DC(193)	M/s. Johnson & Johnson Pvt. Ltd., LBS Marg, Mulund (West), Mumbai-400080	Expressew III Suture Needle	a retractable needle which is used with expressew III flexible Suture Passer designed to pass 2-0 to #2 braided surgical through tissue in either arthroscopic or open surgerv	Not Regulated	03.09.2015

93	29/Misc./3/2015-DC(158)	M/s. Meril Endo Surgery Pvt Ltd., Survey No. 135/2/B and 174/2, Third Floor, E1-E3, Meril park, muktanand Marg, Chala, vapi, Dist. Valsad-396191	Ligating Clips	used in surgery for vessel closer etc., are regulated as drugs under the category of surgical Ligatures (Schedule C)	Regulated	03.09.2015
94	29/CDSCO/Govt./11/2015-MD	The Deputy commissioner of customs, A R Cargo Complex, Sanganer , Jaipur, Rajasthan	Orthodontic items - brackets, archwires, buccal tubes and intra oral products		Not Regulated	10.08.2016
95	29/Misc./3/2015-DC(142)	M/s. Meril Life Sciences Pvt. Ltd. Survey no. 135/2/A, near g m bilakhia stadium muktanand marg chala vapi - 396191	Intra coronary Shunt		Regulated	08.09.2015
96	29/Misc./3/2015-DC(213)	The Drugs Controller & Licensing Authority, Office of the Drugs Controller, Government of karnataka, Place Road, bangalore -560001	Insupen EX	which is an easy to use reusable insulin pen that can deliver insulin doses in increments of 1 unit to be used with prefilled 3 ml insulin cartridges for use in the home environment to aid and support prescribed treatment and therapy	Not Regulated	21.09.2015
97	29/Misc./3/2015-DC(215)	M/s. KAI Manufacturing India Pvt. Ltd., Karan Singh Farm, KH No. 683, Near Farm No. 36 & 37, Shivaji Marg, Westend Greens, Rangpuri, New Delhi-110037	1. Surgical Blades 2. scalpels 3. safety scalpels 4. Biopsy Punches 5. Biopsy Punch with Plunger System 6. Dermal Currettes 7. Micro Surgical Scalpels		Not Regulated	21.09.2015
98	29/Misc./3/2015-DC(220)	M/s. Sesderma India Pvt. Ltd., 6/1517, Devika Tower-6, Nehru Place, New Delhi-110019	Nanopore Turbo-Roller	which is an electrically Operated micro dark spots ecorrector device for aesthetic/cosmetic applicator of the skin	Not Regulated	29.09.2015
99	29/Misc./3/2015-DC(190)	M/s. Mediserve, G-5, Pratap Bhawan , 5, Bahadur Shah Zafar marg, New Delhi-110002	Tubular Bandages - Verba, stulpa-fix and lastogrip	used as support and to provide relief to surgical wounds	Not Regulated	29.09.2015
100	29/Misc./3/2015-DC(216)	M/s. India Medtronic Pvt. Ltd., 1241, Solitaire, Corporate Park, Bldg. No. 12, 4th Floor, Andheri (East), Mumbai-400093	Visualase cooled laser applicator system	used to necrotize or coagulate soft tissue through intestinal irradiation or thermal therapy in medicine and surgery in cargo-vascular thoracic surgery, dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, pulmonology, radiology, head and urology for the wavelength range of 800nm through 1064nm	Regulated	29.09.2015
101	29/Misc./3/2015-DC(227)	The Director, FDA, Goa	AED (Automated external defibrillator) machine	which is a portable device that checks the heart rhythm by sending an electric shock to the heart to try to restore a normal rhythm	Not Regulated	29.09.2015

102	29/Misc./3/2015-DC(217)	M/s. Dr. Schumacher India Pvt. Ltd., 2A, 2nd Floor, 164, M.G.Road, Pune-411001	Cleanisept Wipes Maxi	having bactericidal, fungicidal and virus inactivating properties which is used for the rapid disinfection and cleaning of alcohol-sensitive medical devices, medical equipment as well as of other alcohol-sensitive surfaces	Regulated	29.09.2015
103	29/Misc./3/2015-DC(219)	M/s. Utanco India, 13, tarun enclave, near pushpanjali, pitam pura, delhi-110034	Orthopaedic casting tapes & splint	intended for use in the construction of orthopaedic casts, temporary immobilization of fractures, sprains and strains	Regulated	06.10.2015
104	29/Misc./3/2015-DC(228)	M/s. Sceptre Chemicals Inc., House no. 8 A, 2nd Floor, Siri Nagar Colony, Near Shiva Mandir, Delhi-110052	Citric Acid Solution (Disinfectant)	used for disinfection of hemodialysis machine	Regulated	06.10.2015
105	29/Misc./3/2015-DC(224)	M/s. Allergan Healthcare India Pvt. Ltd., No.3, Kasturba Road, Level 2, Pretige Obelisk, Bangalore-560001	Hyaluronic acid 15 mg + Lidocaine Hydrochloride 3 mg (Juvederm VOLBELLA with Lidocaine) and products Hyaluronic Acid 17.5 mg + Lidocaine hydrochloride 3 mg (juvederm VOLIFT with Lidocaine) concentration		Not Regulated	06.10.2015
106	29/Misc./3/2014-DC(125)	M/s. Delhi Eye Zone Pvt. Ltd., D-114, (G.F.), Iajpat nagar-I, New Delhi-110024	Ferrara Ring- an intraconal Implants	used for correction of pathological tissue deformities of the cornea	Regulated	13.10.2015
107	29/Misc./3/2014-DC(125)	M/s. Care Group India, A unit of polymer technologies INTL, Block no. 310, village sim of dabhasa, Ta Padra, Dist. Vadodara-391440	conical inlay	used for improving the depth of focus by cutting the unnecessary light entering in the eye	Regulated	13.10.2015
108	29/Misc./3/2014-DC(125)	M/s. Emergo (india) Consulting Pvt. Ltd., 8/1, First Floor, Vasavi Colony, Kakaguda, Near Picket, Secunderabad, MCH-Circle-7, mandal, Hyderabad - 500009 A.P.	Presbia Flexivue Microlens	indicated to improve near vision in adult presbyopic subjects	Regulated	13.10.2015
109	29/Misc./3/2015-DC(221)	M/s. Chemours India Pvt. Ltd., 6th floor, Tower-C, DLF cyber greens, sector-25A, DLF city phase -III, gurgaon-122002, haryana	Relyon perasafe-medical device sterilant	used for sterilization on non-surgically invasive medical devices such as gastroscope or bronchoscope endoscope, semi-critical medical devices and may be used as surface disinfectant for decontamination of mycobacteria and clostridium difficile in high risk areas such as infectious disease isolation wards and laboratories	Regulated	13.10.2015
110	29/Misc./3/2015-DC(223)	M/s. Johnson & Johnson Pvt. Ltd., LBS Marg, Mulund (West), Mumbai-400080	Temporary Cardiac Pacing Wire	intended for use in temporary cardiac pacing or monitoring	Not Regulated	14.10.2015

111	29/Misc./3/2015-DC(238)	M/s. Global Medicare, Unit No. 1 & 2, Bawa Potteries Compound, Aruna Asaf Ali Marg, Vasant Kunj, New Delhi-110070	Ultroid (Hemorrhoid Management System)	which is an assembly of electrotherapeutic devices to apply a galvanic direct current to the mucosal tissue and indicated for coagulative hemostatic therapy of internal hemorrhoids, grades I, II, III and IV	Not Regulated	09.11.2015
112	29/Misc./3/2015-DC(237)	M/s. Innogen Life Sciences Pvt. Ltd., K-384, Surajpur Site V, Kasna Industrial area, greater Noida -201308	1. adhesive Non-woven rolls 2. Absorbent pad rolls I.V. dressing (sterile) I.V. dressing (Non sterile) 5. self-adhesive surgical wound dressing (sterile) 6. foam dressings (sterile)	1. Raw material for post operative surgical wound dressings 2. Raw material for post-operative surgical wound dressings 3. a. Fixation of I.V.Cannula b. these are suited for post-operative use. They are useful in accident & emergency for cuts, lacerations and sutured wounds. c. fast, efficient & aseptic protection of the puncture points: parenteral deeding, biopsy & dialysis d. dressing for ambulatory surgery, post-surgery, coeliosurgery. 4. fixation of I.V. cannula 5. a. wound dressings for surgical wound/post operative wound dressing. b. to dress post-operative wounds, minor cuts, abrasions, lacerations and puncture sites where a water-resistant dressing aids in the prevention of bacterial contamination is required. c. may be used as secondary dressing over gels,	Regulated	09.11.2015
113	29/Misc./3/2015-DC(120)	M/s. Paseca Healthcare LLP., Factory: K-68, Sector-3, Bawana Industrial Area, new Delhi - 110039	Surgical dressings made up of Oxidized Regenerated Cellulose and Oxidized Cellulose		Regulated	09.11.2015
114	29/Misc./3/2015-DC(236)	M/s. Dentsply India Pvt. Ltd., Kh. No. 66/20 & 66/11/2, Gali No. 2, Main Rohtak Road, Mundka Industrial Area, New Delhi-110041	Dental filling materials, cementing material, impression materials	used in dentistry	Not Regulated	09.11.2015
115	29/Misc./3/2015-DC(243)	Shri Praveen Agarwal, Agarwal Jetley & Company advocates, A2/78, Safdarjung Enclave, New Delhi-110029	Product 'sooma tDCS Stimulator'	delivers a weak electrical current to the brain via non-invasive scalp electrodes intended for treatment of depression	Not Regulated	20.11.2015
116	29/Misc./3/2015-DC(239)	M/s. Paseca Healthcare LLP., Factory: K-68, Sector-3, Bawana Industrial Area, new Delhi - 110039	1. Hydrocolloid Dressing with Foam 2. Dressing Wound 3. Tranparent wound medicated 4. polymen dressing 5. pressing post op medicated		Regulated	20.11.2015
117	29/Misc./3/2015-DC(232)	M/s. Ujjawal Overseas (India) Pvt. Ltd., Part-A, Basement, Plot No. 1 & 2, Block B, Kh. No. 15/7/5/2 & 15/7/8, Raghu Nagar, New Delhi - 110045	Blood Collection Needles	used to collect blood for testing	Regulated	20.11.2015

118	29/Misc./3/2015-DC(217)	M/s. Dr. Schumacher India Pvt. Ltd., 2A, 2nd Floor, 164, M.G.Road, Pune-411001	Cleanisept Wipes Maxi	having bactericidal, fungicidal and virus inactivating properties which is used for the rapid disinfection and cleaning of alcohol-sensitive medical devices, medical equipment as well as of other alcohol-sensitive surfaces	Regulated	17.12.2015
119	29/Misc./3/2015-DC(261)	M/s. Helyxon Healthcare Solutions (P) Ltd., IIT Madras Research Park, No.01, Kanagam Road, Taramani, Chennai-600113	98.6 Fever-watch	used to facilitate monitoring and tracking of the infants or babies temperature	Not Regulated	17.12.2015
120	29/Misc./3/2015-DC(181)	Sh. Major Yogesh Chandra, Sr. Manager, Indian Oil Corporation, Mumbai	water Gel Based Blankets	used as a body wrap to extinguish fires and to cool and moisten burns	Not Regulated	18.12.2015
121	29/Misc./3/2015-DC(189)	M/s. Argon Impex Pvt. Ltd., 17/306D, Valluvassery, Temple Road, N.F. Gate, Tripunithura P.O. Cochin-682301	woodcast Products	are devices indicated for maintenance of immobilization of extremities and for supporting soft and hard tissues e.g. in orthopaedic treatments	Regulated	21.12.2015
122	29/Misc./3/2015-DC(286)	M/s. Instas Life Science Consultancy Pvt. Ltd., No.3, Green Park, Opp. Yugalkunj Society, B/H Prabhupark Society, Naroda, Ahmedabad, Gujarat-382330	BEL-GEN & IGL-1	intended for the flushing and the hypothermic storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage transportation and eventual transplantation into a recipient	Not Regulated	29.12.2015

2016 Database						
S. NO.	File . No.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	29/Misc/3/2015-DC(221)	M/s Chemours India Pvt Ltd., 6th floor, tower-C, DLF Cyber Greens Sector-25A, DLF City Phase-III, gurgaon-122002, Haryana	RelyOn Perasafe-medical device Sterilant	Sterilization on Non-Surgically Invasive Medical devices such as Gastroscope or bronchoscope endoscope, Semi-Critical Medical Devices and may be used as a surface disinfectant for decontamination of mycobacteria and clostridium difficile in high risk areas such as infectious, disease isolation wards and laboratories	<u>Regulated</u>	1/7/2016
2	29/misc/3/2015-DC(292)	Dr. Rajesh chawla, Principal Investigator, M/s Induraprastha Apollo hospitals, Sarita Vihar, delhi-Mathura road, New Dlehi-110076	Pules Oximeters(nonin, masimo and philips)	assess the oxygenation status of patients at the bed side	<u>Not Regulated</u>	1/7/2016
3	29/Misc/03/2013-DC(270)	Dr. S. Manivaanon. DDC(1), CDSCO(SZ), Second floor, Shastri bhawan Annexe, 26, haddows road, Chennai-600006	instruments-Orthopaedic	instruments used for spine and orthopaedic surgery	<u>Not Regulated</u>	1/7/2016
4	29/Misc/3/2016-DC(03)	M/s Rithwik Pharma Pvt Ltd., Plot No.11-13, 160/406, ramprathap Nivas Moyya nagar Colony, Near Asthalakshmi Arch, L.B Nagar, hyderabad, telangana-500074	CP Relief Wand CP 1000(transcutaneous electrical Nerve Stimulator)	Battery operated Electronic device intended for use as an adjunctive therapy for pain management	<u>Not Regulated</u>	1/19/2016
5	29/Misc/3/2015-DC(242)	Shri. S.K Bhandari, Brig DDCDS(E&S), Dte gen of dental services adjutant general:s Branch IHQ of moD(army), L Block New dlehi-110002	Dental Implants	the Dental materials used for restoration of tooth, tooth movement and dental lab work for fabrication of dental	<u>Not Regulated</u>	1/19/2016
6	29/misc/3/2016-DC(026)	M/s Barrocyte consultants Pvt Ltd., 105, first floor, Block No-CHBS near mother dairy, sukhdev vihar CSC, New Delhi-110025	Disinfectants	Aseptoprint-spray Dentiro light dentiro wipes, isorapid floor, or clean plus oricud-multisept plus orolin burbath, opolin intra & oromed Gel are disinfectants	<u>Regulated</u>	16-02-2016
7	29/Misc/3/2016-DC(14)	M/s Delhi Hopistal supply private Limited 101-103, Pal mohan sadan, 26/32, East Patel nagar rajindra place, New Dlehi-110008	Endo staplers	Disposable surgical staplers	<u>Regulated</u>	16-02-2016
8	29/misc/3/2016-DC(30)	M/s Isens Biosensors India Pvt Ltd., unit no.1116-1117, 11th Floor, JMD Megapolis, shona road, Sector 48, Gurgaon-122001 Haryana	Safety lancets, Lancets(Normal) and lancing device	used for blood sampling for diagnostic purpose	<u>Not regulated</u>	16-02-2016
9	29/misc/3/2015-DC(250)	M/s Merck Limited, Shiv sagar Estate, A dr. A.b Road, worli Mumbai-400018	Pyrogen testing(PyroDectect System)	kits/reagent intended to be used for the diagnosis of disease or disorder in human beings or animals	<u>Regulated</u>	16-02-2016
10	29/misc/3/2015-DC(159)	M/s Lensai ophthalmic pvt ltd., A6-101, La habitat, off 100 ft Road thaltej, Ahemdabad-380059	Punctal Occlusion system extended wear synthetic absorbable punctal plug & temporary collagen punctal plugs	veraplug punctal occlusion system vera90 extended wear synthetic absorbable punctal plug & vera C7 temporary collagen punctal plugs intended for the treatment of dry eye syndrome	<u>Not regulated</u>	16-02-2016
11	29/misc/3/2016-DC(12)	M/s Jagat diagnostics private Limited B-82, Industrial Area, G.T karnal Road, New Delhi-33	Lancet	used for blood sampling i	<u>Not regulated</u>	16-02-2016

12	29/misc/3/2015-DC(73)	M/s paul hartmann medical Pvt ltd., B/506, 5th Floor titanium Square, Thaltej Ahmedabad-380059, Gujarat, India	Cosmopore I.V Hydrofilm I.V and Hydrofilm I.V Control	control are surgical dressing materials	regulated	16-02-2016
13	29/misc/3/2016-DC(16)	Dr. Sharmila Jalgaonkar, member secretary, IEC-1, New UG/PG hostel, 20th Story hostel building Ground floor, KEM Hospital, near main boys hostel Dr. SS Roa's marh, Near parel, Mumbai-400012	Smart sense/Picolabs(Point of care testing(POCT)	analyzing blood samples	Not regulated	16-02-2016
14	29/misc/3/2016-DC(23)	M/s Pixel care india pvt ltd., third floor, C-435 Defence colony, New Dlehi-110024	Impact(concussion management platform) and Ufit(Pulse acquisition device)	to measure heart rate, blood pressure and heart anomalies and the device viz impact(concussion management platform) a software based medical device intended to assess the baseline and post concussion state of an individual	not covered under the provisions of DTC act	16-02-2016
15	29/misc/3/2015-DC(287)	M/s troikaa Pharmaceutical Ltd., commerce house-1, satya marg, bodakdev Ahmedabad-380054	Soy Phosphatidylcholine Gel 6&	for treatment of joint pain associated with osteoarthritis	product is not yet approved.	16-02-2016
16	29/misc/3/2016-DC(31)	M/s Sutures India Pvt Ltd., 472 D, 13th Cross, 4th Phase, Peenya industrial Area, bangalore-560058	Proisorb Mesh(Composite of polypropylene and polyglycolic acid)	form 29 for purpose of examination testing and analysis in india	NOC to grant test license in form 29	16-02-2016
17	29/misc/3/2015-DC(152)	M/s Sahaj Regenerative Cell therapeutics LLP 13/2, south tukoganj indor , Madhya Pradesh	Homogenisation/ultrasonic covitation of fat tissue	for homogenisation and ultrasonic cavitation of fat tissue to obtain the stromal vascular fraction	Not regulated	16-02-2016
18	29/misc/3/2016-DC(21)	M/s cytocare technologies Pvt Ltd., Hyderabad	Cryomacs Freezing bags transfer sets and clinimacs reagents	for storage of peripheral blood Stem cells and cord blood stem cells,	regulated	16-02-2016
19	29/Misc/3/2015-DC(157)	M/s Sutures India Pvt Ltd., 472 D, 13th Cross, 4th Phase, Peenya industrial Area, bangalore-560058	Trustat(xxidized Regenerated Cellulose)	surgical dressings	Regulated	23-02-2016
20	29/misc/3/2014-DC(141)	M/s Meril Life Sciences pvt Ltd., Survey no.135/2/A, near G.m Bilakhia Stadium muktanand marg, Chala,Vapi-396191	Myosista Intra Aortic balloon catheter kits	examination testing and analysis of Myosist intra aortic balloon catheter kit	permission to manufacture & sale of the product	23-02-2016
21	29/misc/3/2016-DC(46)	M/s IDS Denmed Pvt Ltd., A-20/3, Ground floor, Mayapuri Industrial Area, Phase-I, New Delhi-110064	Wipes for Disinfection/Cleaning of medical devices	designed to rapidly clean and disinfect areas at great risk	regulated	23-02-2016
22	29/misc/3/2016-DC(45)	M/s Ceragem India Pvt Ltd., 4th Floor, Plot no.58,Sector-44, HUDA, gurgaon, haryana-122002	Ceragem RL1 (ceragem master v3)	automatic thermal masager	Not regulated	23-02-2016
23	29/misc/3/2016-DC(29)	M/s Becton Dickinson India Pvt Ltd., 5th Floor, Signature tower B, South city I, Gurgaon-122001, Haryana	BD CS&T beads for in-vitro diagnostic (Quality control solution)	to be used to monitor daily instrument performance by measuring fluorescence sensitivity and alignment.	regulated	23-02-2016

24	29/misc/03/2013-DC(281)	Shri. Om prakash, Section officer, Ministry of Health and family welfare, Nirman Bhwan, New Dlehi	Left Ventricular Assist devices	used to partially or completely replace the function of a failing heart-used as a bridge to transplant to keep the patients alive till an organ can be found	Not regulated	18-02-2016
25	29/misc/3/2016-DC(55)	M/s Utanco India 13, Tarun Encalve, near Pushpanjali Pitam Pura, Delhi-110034	Green cast orthopaedic artificial limbs making tape	use in he construction of orthopaedic casts, temporary immobilization of fractures, sprains and strains	regulated	01-03-2016
26	29/misc/3/2016-DC(54)	M/s Peches Lifestyles Pvt LTD., 1, dhanvantri, Rambaug lane opp, Mulji Nagar, off S.V Road, Borivali(West), Mumbai-400092	Cryo Slim 2HPS, Oxygen & Water peel Plus LED system Potable ware LED and I-Frax Non-Invasie Radio Frequency Aesthetic system	used for cosmetic purpose	Not regulated	1/3/2016
27	29/misc/3/2016-DC(43)	M/s Covidien Healthcare india Private limited 4th Floor, Tower A & B, SAS tower medanta The medicity complex, sector-38, Gurgaon, Haryana-122001	ligasure curved small jaw open sealer/Divider	Used for general surgical procedures where ligation and division of vessels(up to 7 mm in diameter) tissue bundies and lymphatics	regulated	1/3/2016
28	29/misc/3/2015-DC(249)	M/s Merck Limited, Shiv sagar Estate, A dr. A.b Road, worli Mumbai-400018	Vented Medical Millex filter in India	vented millex-GV filter units are syringe filters used for sterilization of low volume aqueous solutions for direct patient injection, filtration of laboratory solutions, and filtration of clinical solutions where venting and low protein binding membrane are required	Not regulated	11/3/2016
29	29/misc/3/2015-DC(146)	M/s. Agkem Impex Pvt Ltd., 503-504, Rishabh corporate tower, Plot No.16, community centre karkadooma, Delhi-110092	Zirconia Blank, Vintage Art/Hole/MP/ZR/Al, ceramage	ceramage indicatet ofr vennering of metal framework and copings for the preparation crowns and bridges	Not regulated	22-03-2016
30	29/misc/3/2016-DC(64)	Chief Medcial Officer, Office of CMO, Sawai maan Singh Hospital Jaipur, Rajasthan-302004	Heart valves	nil	regulated	22-03-2016
31	29/misc/03/2016-DC(72)	M/s Greiner Bio-One(india) Pvt Ltd., the corenthum, 2111, tower-A, Plot no.A/41, Sector-62, Noida-201301	Lancet	nil	Not regulated	22-03-2016
32	29/misc/3/2016-DC915)	M/s Shakhti Knitting limited Land Marvel Nest F-1,3 first Main Road, indira nagar Adyar, Chennai-600020	Bedsheet & other articles containing chemical salts for home & hospitals uses	bed sheets, pillow covers, pillows 7 mattresses ,Hospital scrubs, Masks, doctor coats, lab coats, patient care gowns, Kitchen aprons, table cloth,Napkins & Towels, Kerchiefs, mittens & gloves, socks, and other article made out of textiltreated with chemical i.e (Dimethyltetradecyl193-trimethoxysilyl) propyl ammoniumchloride, a quaternary ammonium salt(QAS) to be used in hopsitals, patient care homehotels and residence	Not regulated	22-03-2016
33	29/misc/3/2016-DC(63)	M/s Surgiplus, Polt No.2,5th Cross, Ganaprakasam nagar, Puducherry-605008	Connecting tube with & without yankuer	nil	regulated	22-03-2016
34	29/misc/3/2016-DC(83)	M/s Covidien Healthcare india Private limited 4th Floor, Tower A & B, SAS tower medanta The medicity complex, sector-38, Gurgaon, Haryana-122001	Pledgets and trocar	PTFE Polymer pledgets and versaport/Versaport plus bladeless tocar-sutuer and catheter	regulated	22-03-2016
35	29/misc/03/2016-DC(75)	M/s Ace Cardiopathy Solutions Pvt LTD., 704,7th Floor, Kirshna apr Business Square, neata Ji Subhash Place, Delhi-110034	Comfort-In (needle-Fress & easy-Quick Injection system)	contains syringes and adapter used to deliver 0.5ml volumes of various medications(especially insulin) and vaccines subcutaneoulsy	regulated	11/4/2016

36	29/misc/3/2016-DC(93)	M/s Covidien Healthcare india Private limited 4th Floor, Tower A & B, SAS tower medanta The medicity complex, sector-38, Gurgaon, Haryana-122001	PDB(Preperitoneal Dissection balloon) kidney and round shaps balloon	indicated for patients undergoing laparoscopic surgery requiring tissue separation of the extraperitoneal space	regulated	5/4/2016
37	29/msic/3/2016-DC(92)	M/s Covidien Healthcare india Private limited 4th Floor, Tower A & B, SAS tower medanta The medicity complex, sector-38, Gurgaon, Haryana-122001	chronic catheter accessory	used to aid percutaneous insertion of peritoneal	regulated	5/4/2016
38	29/misc/03/2016-DC(80)	M/s B 1 Health 7 Safety pvt ltd., BL House & Safety pvt ltd., New Delhi-11049	Waterjel fire Blankets and Dressing for burns	indicated to cool and soothes both minor burns and moreserious burns	Not regulated	5/4/2016
39	29/misc/03/2016-DC(88)	M/s Covidien Healthcare india Private limited 4th Floor, Tower A & B, SAS tower medanta The medicity complex, sector-38, Gurgaon, Haryana-122001	Y-connectors	used for guiding, positioning and locking guidewires or catheters	regulated	5/4/2016
40	29/misc/03/2016-DC(84)	Dr. Shahid Ali Siddiqui, MBBS MD, prof & head, Department of radiotherapy J.n Medical College & Hospital, Aliderh Muslim University, Aligarh-202002	LED based light source device-LED based intraoral PDT light deliver system used for PDT(photodynamic therapy)	trestment i	Not regulated	5/4/2016
41	29/misc/03/2016-DC(81)	M/s Sarvam Safety equipment Pvt Ltd., L-11, SIDCO Industrial estate Villivakkam, Chennai-600049	Waterjel blankets	Indicated to cool and soothes both minor burns and more serious burns	Not regulated	5/4/2016
42	29/misc/03/2016-DC(42)	M/s Unor Exim Pvt ltd., 403 Kirti Mhal bulding, 19, Rajendra Place, new delhi-110008	PVA Nasal packs/PVA Naal tampons, Invotec internal Nasal Splint & ventilation tube	intended for controlling nasal hemorrhage, Septoplasty, rhinoplasty and intra-nasal surgical	regulated	12/4/2016
43	29/misc/3/2016-DC(101)	M/s Unicorn Denmart Ltd., 3, Local Shopping centre, Mor land Near, J Block, DDA market near ranjendra Nagar, New Delhi-110060	Dental Material	used as dental restorative material for veneering of metal framework and opings for preparation crowns and bridges	Not regulated	12/4/2016
44	29/misc/03/2016-DC(94)	M/s Sahotaz, 214C/2 Guatam nagar, New Delhi-110049	Silky cup(reusable Menstrual Cup)	used to collect menstrual fluid during menstruation as a viable alternative to sanitary nakings, cloth pads and tampons	Not regulated	12/4/2016
45	29/misc/03/2016-DC(96)	M/s Event medi Systems, 218, vishal tower, District centre, Janakpuri, New Delhi-110058	Manifold	manifold inteded for flow control and as delivery devices for I.v fluids injection in angiographic procedures	regulated	12/4/2016
46	29/misc/3/2016-DC(08) part-1	M/s Hindustan medi-needs flat no.2132, Sector-D, Pocket-2, Vasant Kunj, New Delhi-110070	disposable swabs	disposable swabs containing one pad satuated with 70% isopropyl alcohol, intended for leaning the skin at the site of injection before giving the injection	regulated	19-04-2016
47	29/misc/3/2016-DC(100)	M/s Unicorn Denmart Ltd., 3, Local Shopping centre, Mor land Near, J Block, DDA market near ranjendra Nagar, New Delhi-110060	Prime Dental VLC(Hyrid Composite kit, Nano-hybrid composite kit, flowable Kit, Enamel bond adhesive)	used as filler/Restorative material for dental cavities	Not regulated	21-04-2016

48	29/misc/3/2016-DC(113)	M/s S. Three Sales International pvt Ltd., M10, Old DLF Market, Sector 14, Gurgaon	Clave needle free connector	intended for use as an accessory to intravascular administration set for the administration of fluids to patient through a cannula placed in the vein or artery	regulated	25-04-2016
49	29/misc/3/2016-DC(103)	M/s Mitra Medical Services LLP, B-226, Okhla Industrial Area, phase-1, new Dlehi-110020	Wave guidewire	wave guidewire intended to be used as an accessory for endoscopes	regulated	26-04-2016
50	29/misc/03/2016-DC(89)	M/s Covidien Healthcare india Private limited 4th Floor, Tower A & B, SAS tower medanta The medicity complex, sector-38, Gurgaon, Haryana-122001	Auto Suture Surgiwand	used in laproscopic procedures as a multi-purpose operating tool with irrigation and suction capabilities	regulated	26-04-2016
51	29/misc/03/2016-DC(87)	M/s Covidien Healthcare india Private limited 4th Floor, Tower A & B, SAS tower medanta The medicity complex, sector-38, Gurgaon, Haryana-122001	LF-1212 Ligasure curved small jaw open sealer/divider is a bipolar electrosurgical instrument	intended to be used with the force triad energy platform	Not regulated	28-04-2016
52	29/misc/03/2016-DC(86)	M/s Covidien Healthcare india Private limited 4th Floor, Tower A & B, SAS tower medanta The medicity complex, sector-38, Gurgaon, Haryana-122001	Endo catch Gold	used for safe, Convenient removal of tissue specimens such as the appendix, and ectopic pregnancy, gall bladder, gal stones, lymph nodes, ovaries, small sections of bowel and other tissues structures	Not regulated	4/5/2016
53	29/misc/03/2016-DC(90)	M/s Covidien Healthcare india Private limited 4th Floor, Tower A & B, SAS tower medanta The medicity complex, sector-38, Gurgaon, Haryana-122001	Endo bag Specimen retrieval system	intended for use in laproscopic procedures where removal of tissue or debris from the abdominal cavity is desired	Not regulated	4/5/2016
54	29/misc/3/2016-DC(122)	M/s edwards Lifesciences(India) private Limited E.F 201-204, remi bizcourt, Plot No.9 shah industrial estate, off veera desai road andheri(w), Mumbai-400058	Disposable pressure transducer; model no. PX 260	disposable pressure transducer Model No. PX 260 used to measure arterial pressure or central venous pressure in human beings	regulated	4/5/2016
55	29/misc/3/2016-DC(99)	Dr. Sayan Basu, Member secretary ethics Committee LV prasad eye institute banjara hills Hyderabad-500034	RHCIII-MC Bio-Synthetic cornea in patients requiring deep anterior lamellar keratoplasty(DALK)	nil	Not regulated	4/5/2016
56	29/misc/3/2016-DC(130)	M/s Peches Lifestyles Pvt Ltd., 1, dhanvantri, Rambaug lane opp, Mulji Nagar, off S.V Road, Borivali(West), Mumbai-400092	Medical equipments for cosmetics treatment(AML1,2,3,4,5,6,7,8)	used for cosmetic purpose	not regulated	4/8/2016
57	29/misc/3/2016-DC(125)	M/s Kay & company, 25, netaji Subhaseh marg, new delhi-110002	medical equipments surgical instrument and hospital rubber goods	nil	Not regulated	4/5/2016
58	29/misc/03/2016-DC(124)	M/s Chrysalis Healthcare Private Limited, A-5, Golf View Apartment saket, New Delhi	MiniMizer gastric Ring	Indicated for sustain 7 effective weight loss in bariatric surgery	Not regulated	10/5/2016
59	29/misc/03/2016-DC(962)	M/s cliniRx tangent Research Private Limited patriot House, 4th Floor 3, bhadur Shah Zafar marg, New Dlehi-110002	Minimally Invasive Micro Sclerostomy(MIMS)	intended for the reduction of elevated intraocular pressure(IOP)	Not regulated	10/5/2016

60	29/misc/3/2015-DC(133)	M/s Helico International, Unit 2, C-30, KSSIDC Industrial Area, Doddaballapura-561203, Bangalore rural	Poly urethane fam dressing kit	drain the chronic wounds such as diabetic foot ulcers, pressure sores etc	regulated	10/5/2016
61	29/misc/03/2016-DC(131)	M/s Duraent Biologicals Lids., T & a 12A, 2nd Floor, Jain enclave T & A Plaza < Madhapur, Sharlingampalli Mandal, Ranga Reddy Dist Hyderabad-500081	Eurocollins A, Eurocollins B, Servator HTK, Servator C and Servator P)	used for the flushing and cold storage of organs like heart lung kidneys, liver and pancreas	not regulated	10/5/2016
62	29/misc/03/2016-DC(121)	M/s. Concord Drugs Limited 3-11-1/1, opp Kamineni Hospital, L. B. Nagar, Hyderabad-500074	Amcrylate Bio-Adhesive -Amyl 2-Cyanoacrylate	intended to be used as bio-adhesive	Not regulated	10/5/2016
63	29/misc/3/2015-DC(194)(214)(225)	M/s Accredited Consultants Pvt Ltd., D-29, First floor, Acharya Niketan, Mayurvihar, Phase-I, New Delhi-110091	Adhesive Plaster, bandages, casting taps and splint	nil	Regulated	10/5/2016
64	29/misc/3/2016-DC9104)	M/s Mitra industries Pvt Ltd., 14/4, Delhi-Mathura road, Faridabad Haryana-121003	Raw material used in manufacturing of Blood Bags & dialysis bags	nil	Not regulated	17-05-2016
65	29/misc/3/2016-DC(104)	M/s Mitra industries Pvt Ltd., 14/4, Delhi-Mathura road, Faridabad Haryana-121003	Polyether ether ketone (PEEK tubing extruded), Sheath (Plastic tube) and Nitinol wire (AS Brawn Bright)	used for the manufacturing of non-cardiac stents	Not regulated	17-05-2016
66	29/misc/03/2016-DC9146)	M/s Emergo (India) Consulting Pvt Ltd., H.No. 8/1, First Floor, Vasavi colony, Kakaguda, near Picket Secunderabad, MCH Circle-7 Mandal, Hyderabad-500009	Endometrial curette and pipettes	use of this medical device is endometrial biopsy and mechanical removal of the cumulus cell layers of the oocyte	Not regulated	17-05-2016
67	29/misc/03/2016-DC(147)	M/s Pro Medic devices., A-13 East Krishna Nagar Swami Dyanand Marg, Delhi-110015	pacemaker	nil	Not regulated	17-05-2016
68	29/misc/3/2016-DC(91)	M/s Covidien Healthcare India Private Limited 4th Floor, Tower A & B, SAS tower Medanta The Medicity complex, Sector-38, Gurgaon, Haryana-122001	SILS PORT	indicated for multiple instrument or camera access to the abdominal cavity through a single incision for performing minimally invasive laparoscopic procedures	Not regulated	6/6/2016
69	29/misc/03/2016-DC(85)	M/s Covidien Healthcare India Private Limited 4th Floor, Tower A & B, SAS tower Medanta The Medicity complex, Sector-38, Gurgaon, Haryana-122001	Bluntport and blunt tip trocar, thoracoport trocar and visiport plus optical trocar with fixation cannula	used in variety of gynecologic general thoracic and urologic endoscopic procedures	regulated	6/6/2016
70	29/misc/3/2016-DC(167)	M/s Bornlife prosthetic & orthotic ins, H-2 Near Gurudwara, Lajpat Nagar-I, New Delhi-110024	Rehabilitation goods (prosthetic hip, knee joint, foot, artificial limbs and its accessories, orthopedic braces & supports, orthotic devices, silicone products, wheel chairs,	used for externally artificial body parts and assistive device by handicap persons).	Not regulated	9/6/2016
71	29/misc/03/2016-DC(172)	The Drugs Controller & Licensing Authority, Office of the Drugs Controller for the State of Karnataka, Post Bag No 5377, Palace Road, Bangalore-560001	Polyurethane foam dressing kit (Non-Sterile)	nil	regulated	10/6/2016

72	29/misc/3/2016-DC(176)	M/s. Accredited consultants Pvt LTd., d-29, 1st floor, Acharya Niketan mayur Vihar, Phase-I, Delhi-91	Dental impression material and mixing equipments	used as dental restorative material and dental equipments	Not regulated	13-06-2016
73	29/misc/03/2016-DC(177)	M/s MedsurgeInd private limited New No.7, old no.4, I cross Street Shashthri nagar, Adyar, Chennai-600020	Surgical Disposable product(Plastibell amni hook umbilical cord clamp, Urine bag	used during surgery	not regulated	13-06-2016
74	29/misc/3/2016-DC(164)	M/s Cybernoid healthcare pvt Ltd., Plot No.70, First Layout, teachers colony, Kolathur Chennai-600099	Robotic exoskeleton orthosis(Cybolimb)	used to mobilize patients of spinal injury with bilateral lower limb parapysis	Not regulated	14-06-2016
75	29/misc/03/2016-DC(191)	M/s Maser Electronics Pvt Ltd.,76, Vishal Industrial estate, opp CEAT Tyres, Bhandup(W), Mumbai-400078, india	Airborne ultrasound-GlybetaC Aerostimulator	glybetac aerostimulator utilizes in the ultrasound energy to improve and enhance the cel permeability and help in the transportation of drugs	Not regulated	14-06-2016
76	29/misc/03/2016-DC(187)	M/s St.Luke Med devices pvt Ltd., ISHI Land", No.18, tagore nagar 1st Street, Ayanavaram, Chennai-600023	Prefilled Humidifier with adaptor	used to humidify the respiratory gas	Not regulated	14-06-2016
77	29/misc/03/2016-DC(182)	M/s Pure tech health,pant hospital, bhua rani, Kashipur Road, Rudrapur, Uttarakhand-248197	Movas-Electric potential therapy equipment	nil	Not regulated	14-06-2016
78	29/misc/3/2016-C(165)	M/s Unistar tools and engineering, 208, plot no.14, gupta Arcade. Maypuri indl area Phase-II, new Delhi-64	Orthopaedic saw blades	used for bone surgery(for ctting)	Not regulated	14-06-2016
79	29/misc/3/2016-DC(129)	M/s encarta Pharma Pvt ltd., Shristi No. 21 3rd floor, 24th Main Road JP Nagar 6th Phase, Bangalore-78	Hyper-CL contact Lens	for corneal dystrophies	Not regulated	14-06-2016
80	29/misc/03/2016-DC(175)	M/s Raj Agencies, Shop No.58, ganesh Plaza, (4th floor) No.3, nyniappa nicken street, Chennai-600003	Nebulizer mask, Oxygen masj, Nasal cannula and circuit	nil	Not regulated	14-06-2016
81	29/misc/03/2016-DC(174)	M/s hi-tech Advance products, P-27, Sukhlia ,Near bapat Nursing Home, indore-10(MP)	Syringe and needles for veterinary use	DAN-Inject injection needles b) DAN-inject Dart Syringes c), DAN-Inject blowpipe systems and d) DAN-Inject carry and handling system-Model Rug used for treatment of wild and Zoo animals	regulated	14-06-2016
82	29/misc/03/2016-DC(186)	M/s Becton Dickinson India Pvt Ltd., 5th Floor, Signature tower B, South city I, Gurgaon-122001, Haryana	BD Odon Device for assisted vaginal delivery	intended to assist skilled attendant in vaginal delivery	Not regulated	14-06-2016
83	29/misc/03/2016-DC9170)	M/s Accredited Consultants Pvt Ltd., D-29, First floor, Achharya Niketan, Mayurvihar, Phase-I, New Delhi-110091	ECG recorder & tansmitter mfd	used as ECG Recorder & Transmitter	not regulated	14-06-2016

84	29/misc/03/2016-DC9155)	M/s Indo-US Supersociality hospital, A unit on nano hospital pvt ltd., # 7-1-57 B&C, Shyam karan road, Anand Bagh, Ameerpet, Hyderabad-500016	hyath cancer Annihilation machine for cancer treatment	used in cancer treatment	Not regulated	15-06-2016
85	29/misc/03/2016-DC(169)	M/s MN Solutions, space No.512, 5th Floor Shahpuri tirath Singh Tower Plot No.58, block-C, DDA community Centre, janakpuri, New Dlehi-110058	Acrylic teeth-goldent classic acrylic teeth	used in prosthetic dentures	Not regulated	15-06-2016
86	29/misc/03/2016-DC(189)	M/s Toshbro Medical Pvt Ltd., 1001-1002, vikram tower 16 Rajendra Place, new Delhi-110008	Aneurysm clips, Drill Burrs/cutters, perforators & craniotomes	nil	Not regulated	21-06-2016
87	29/misc/03/2016-DC(196)	M/s goldwin Medicare Ltd., 2, Doctor house, 2nd Floor, 124 Perin Nariman Street, fort Mumbai-400001	Synthetic casting tape	nil	regulated	21-06-2016
88	29/misc/3/2016-DC(198)	M/s KPM Healthcare f-33, Second Floor, DSIDC Complex, near udyog nagar Metro Station, rohtal road, Delhi-110041	Drip chamber spike luer lock/luer slip connector, tube roller clamp and flow regulator) pU/PE/ silicone tube 3) PU spiral/Straight tube, Male /female luer lock connector4) male/female luer lock, parallel connector 5) needle free valve	intended for manufacturing of finished medical devices	Not regulated	24-06-2016
89	4-MD/CT-131/2015-DC	M/s Alfa corpuscles Private Limited 25/36, East patel Nagar New Dlehi-110008	Enject safety syringe	Clinical trial in respect of product i.e. enject safety syringe	regulated	9/6/2016
90	29/misc/3/2015-DC(258)	M/s KCI Medical india Pvt Ltd., no.1, Ramachandra Comple, 1st floor, 1st Cross M.S Nagar Opp Ayappa temple, banglore-560033	V.A.C Verlink installation cassette	disposable component to be used with VAC ultra wound therapy system	Not regulated	22-06-2016
91	29/misc/03/2016-DC(173)	M/s Shield Healthcare Pvt Ltd., AVN complex, vanagram Serivce Road, Vanagaram, Maduravoyal, Chennai-600095	Biguanelle and andrositol lab	biguanelle(hydroxyethyl cellulose+ lactic acid+ glycerol+ KCl+Sodium edetate+ PHMB) use for the treatment of vulvovaginitis and cervicovaginitis and andrositol lab (Myo-inositol+ Naci) used for the treatment of mae seminal fluid	regulated	30-06-2016
92	29/misc/03/2016-DC(195)	M/s Hindustan syringes & Medical devices Ltd., GL-3, Ashoka estate, 24, barakhamba raod, New Dlehi-110001	evacuated Blood collection tube	Evacuated blood collection tube without needle	Not regulated	1/7/2016
93	29/misc/3/2016-DC(132)	M/s Halyard health India Pvt Ltd., world trade Centre tower-1, unit-308, Kharadi, Pune-411014	Integuseal Microbial Sealant which a cyanoacrylate	intended for use after typical pre operative skin preparation	regulated	11/7/2016
94	29/misc/03/2016-DC9204)	M/s Vygon India Pvt Ltd., B-17, infocity, Section -34, gurgaon-122001(Haryana)	a) Endotracheal tube b) Feeding tube and c) Swivel connector d) urine collection bag, e) Filters	nil	a), b) c) - regulated d), e) Not regulated	12/7/2016

95	29/misc/3/2016-DC(21)	M/s cytocare technologies Pvt Ltd., Hyderabad	Cryomacs Freezing bags transfer sets and clinimacs reagents	intended for storage of peripheral Blood Stem cells and cord blood stem cells	regulated	15-07-2016
96	29/misc/03/2016-DC(179)	M/s Regency Lifesciences India Pvt Ltd., No.8, 4th A Cross, 5th Main, HRBR 2nd Block, Kalyan Nagar, bangalore-560043	New gel+(Silicone gel +vitamin E gel)	used in management of hypertrophic and /or scars	regulated	19-07-2016
97	29/misc/03/2016-DC(178)	m/s Feron life Sciences(P) Ltd., B-1, yadav park, Main Rohtak road, Opp.Metro Pillar No. 436, nangloi, Delhi-110041(india)	Hemoperfusion Cartridge and disposable plasma bilirubin perfusion Adsorption column	intended for removal of bilirubin and bile acids	regulated	19-07-2016
98	29/misc/03/2016-DC(157)	M/s Mod Medicare Systems Pvt Ltd., GH-2/81-B, Paschim Vihar, New Delhi-110063	Smart site with small bore extension set, y extension set with two smartsite and tri-port extn set with two smartsite and c) tri-port wxtn . Set with 3 smart site)	nil	regulated	19-07-2016
99	29/misc/03/2016-DC(171)	M/s Allergan India Private Limited Level 2, Prestige Obelisk, No.3 Kasturba Road, Bangalore-560001	Glaucoma gel implant Xen 45(Xen gel implants)	used to reduce IOP in patients with primary open angle glaucoma (POAG)	regulated	19-07-2016
100	29/misc/03/2016-DC(207)	m/s Aakaar Medical technologies Pvt Ltd., A-801, heritage Plaza, telli Galli Cross Road, Andheri(E), Mumbai-400069	Hairstetics hair implant	to treat alopecia	not regulated	19-07-2016
101	29/misc/03/2016-DC(219)	M/s ventura business Solutions, 109/13, First floor, amritpuri-B, Opp iskon temple, east of kailash, New Delhi-110065	Wound healing system	used to heal chronic ulcers, reduce lesion size and wound pain and accelerate tissue re-growth	Not regulated	22-07-2016
102	29/misc/03/2016-DC(224)	M/s Sesderma India Pvt ITd., 6/1517 Devika tower -6 Nehru Place, New Delhi-110019	Nanopore stylus	used for aesthetic/Cosmetic application of the skin	Not regulated	22-07-2016
103	29/misc/03/2016-DC(222)	M/s live2give international Marketing pvt Ltd., Industrial area, plot no.E-216, Focal point Phase 8-B, Mohali-160058 Punjab	Anti-Snore products	used to help prevent snoring and facilitate breathing and hongseng callus remover for removing dead skin	Not regulated	22-07-2016
104	29/misc/03/2016-DC(138)	M/s halyard health inida pvt ltd., World trade center, tower-1, Unit-308, Kharadi, Pune-411014	oral care products	oral care products Halyard Yankauer, halyard suction handle, Halyard oral care swab and halyard oral care suction toothbrush	Not regulated	22-07-2016
105	29/misc/03/2016-DC(226)	M/s Accredited Consultants Pvt Ltd., D-29, First floor, Acharya Niketan, Mayurvihar, Phase-I, New Delhi-110091	Universal (UNI) handle(ICV0664) and holder handle(P0593)	used as accessory instruments I hear valve replacement surgeries	Not regulated	22-07-2016
106	29/misc/03/2016-DC(162)	M/s BD India Pvt ltd., 204, Tolstoy house, 15, tolstoy marg, new delhi-110001	PleurX Catheter System-drainage kit , pleurX procedure pack & pleurX lockable drainage line kit consisting of self-adhesive dressing and Alcohol pads	nil	regulated	22-07-2016

107	29/misc/03/2016-DC(227)	M/s Lifesol Medical private ltd., Okhla Phase-2, New Delhi	Lifesol neutraflow single with non DEHP extension line	single use disposable device intended for the withdrawal of fluids continuous or intermittent administration of fluids	regulated	26-07-2016
108	29/misc/3/2016-DC(218)	M/s Aramex Trading co., 9-Ashok Nagar, Lucknow	Dental material Ahfil	used as dental restorative material	Not regulated	2/8/2016
109	29/misc/03/2016-DC(08) Part-I	M/s J. Mitra & Bros., P.O Box-2809, 20 Double storey market, New Rajendra Nagar, New Delhi-110060	Euroset Mini Arterial filter	used in pediatric open heart surgeries in children suffering from heart diseases	Not regulated	4/8/2016
110	29/misc/03/2016-DC(180)	M/s Maquet Medical India Pvt Ltd., II floor, Mehta Trade Centre" No.1, shivaji Colony, Sir M.V. Road Andheri(E), Mumbai-400099	Vasoview & Endoscopic vessel Harvesting System, Vasoview Hemopore 2 Endoscopic Vessel harvesting and 7mm Endoscope	used for minimal invasive surgery	Not regulated	8/8/2016
111	29/misc/03/2016-DC(83)	M/s covidien Healthcare India Pvt Ltd., 4th Floor, Tower A & B, SAS tower, medanta the medicity complex, Sector-38, Gurgaon-1220011	trocar	nil	regulated	8/8/2016
112	29/misc/3/2016-DC(253)	Dr. Haresh Bhalodiya Principal Investigator Saviour Multispeciality hospital, near bhart petro pump, near lakhudi talaw, stadium road, navrangpura, Ahmedabad-380014	freedom total knee system in total knee arthroplasty	surgeons want to conduct the study on a retrospective cohort of the patients operated by the surgeon in the year 2010-11	approval	9/8/2016
113	29/misc/03/2016-DC(126)	M/s Event medi Systems, 218, vishal tower, District centre, Janakpuri, New Delhi-110058	Balloon inflation device(indeflator) and Haemostatic valve kit(Y connector Kit)	nil	Regulated	9/8/2016
114	29/misc/03/2016-DC(239)	M/s Scitra International No.5, Silko valley, Sector-127 S.A.S Nagar, Punjab-140301	Soft cast Bandage	used under POP bandage to give cushioning effect to the patient	Not regulated	11/8/2016
115	29/misc/03/2016-DC(235)	M/s Zuventus healthcare ltd., T-184, MIDC, Bhosari, Pune-411026	SiGyn vaginal gel	used for vaginal symptoms in Genitourinary Syndrome during menopause(GSM)	regulated	18-08-2016
116	29/misc/03/2016-DC(215)	M/s Morulaa health tech Pvt Ltd., Plot no.38, first floor, rajeswari Street, Santhosh Nagar, Kandanchavdi, Chennai-600096	Megadyne Medical product	used during general and laproscopic surgical procedures	Not regulated	18-08-2016
117	29/misc/03/2016-DC(225)	M/s Vasu vaccine & Speciality Drugs, Vasu's Pharma House, 3-6-516/4, 5th Floor, Street No.6, himayatnagar, MCH Circle-3, mandal, Hyderabad-500029	Rxvoice, Rxtunnel and Rxnasalve	for ENT application	regulated	23-08-2016
118	CLAA/MD/HR/01/2015-DC	M/s prymax healthcare LLP, Plot no. 53/17, industrial area NIT Faridabad haryana(India)-121001	Disposable persfusion set	Heart lung pack and angio kit including accessories viz, arterial & venous pump lines, arterial filter bypass loops, Y connectors, perfusion tubing manifold etc	regulated	9/8/2016

119	29/misc/03/2016-DC(184)	M/s Hollister Medical India Private Limited, Plot No.27, Sector 5, Phase-II, HSIIDC Growth Centre Bawal 123501, Haryana	Benzalkonium chloride seabstick and non-sterile lubricating jelly	nil	NOC for the product	5/9/2016
120	29/misc/03/2016-DC(09)	M/s Dhiti Biotech(India) Pvt ltd., The director, Z-29, basement Okhla Industrial area, Phase II, New Dlehi-20	Disposable infusion pumps	used for self administration analgesic infusion	regulated	6/9/2016
121	29/misc/03/2016-DC(244)	M/s. Access Devices, 28, 12th cross , Indiranagar, 1st stage, Bangalore 560038	Scalp cooling system	used for prevention of chemotherapy induced alopecia	not regulated	12/9/2016
122	29/misc/03/2016-DC(254)	M/s. Lotus Surgical Pvt. Ltd., Khasra No. 105/1 & 2, Twin Industrial Estate, Selaqui, Dehradun-248197	Absorbable Hemostat-Sterilized Oxidized Regenerated Cellulose (ORC) USP	used adjuvantly in surgical procedures to assist in the control of capillary, venous and small arterial hemorrhage when ligation or other conventional methods of control are impractical or ineffective and disposable circular stapler intended for the creation of end to end, end to side and side to side anastomosis in both open and endoscopic surgeries throughout the alimentary tract	regulated	12/9/2016
123	29/misc/03/2016-DC(242)	M/s. Diacare Solutions, 104, Kesarinath CHS , Opp. Vijay Sales, S.V. Road, Goregaon (West), Mumbai-400062	(A) Hemodialysis Machine terminal disinfectant with citric acid 21% (B) Hemodialysis Machine Disinfectant with Peracetic acid (C) cold Sterilant for Dialyzer	(A) Used for cleaning hemodialysis , thermochemical disinfection, (B) used for cleaning hemodialysis, cold disinfection (C) used for reprocessing dialyzers machine	regulated	12/9/2016
124	29/misc/03/2016-DC(216)	M/s. Pyrex Exports, 114/2, Krishan Kunj, 7 Civil Lines, Roorkee-247 667	(A) Dental Material Glass Lonomer cement (B) Alvo Dough which is a dental haemostatic materila having antimicrobial action due to presence	(A) Used for fixation of crown and bridges (B) used for treatment of dry sockets, post extraction dressing	(A) not regulated (B) regulated	12/9/2016
125	29/misc/03/2016-DC(246)	M/s. Transcath Therapeutics LLP, 1203, Mars, Rajhans Campus, Opp. Rajhans Multiplex, Pal-Hazira Road, Surat - 395009, Gujarat	(A) PleuroTalc (B) embolus PVA embolization particles	(A) used for chemical pleurodesis, malignant pleural effusion, spontaneous pneumothorax and (B) embolus PVA embolization particles used for embolization of peripheral hypervascular tumors including leiomyoma uteri and peripheral arteriovenous malformations (AVMs)	regulated	12/9/2016
126	29/misc/03/2015-DC(204)	M/s. UE Life Sciences India Pvt. Ltd., A-102 Universal Paradise, Nanda Patkar Road, Vile Parle (East, Mumbai-400057	iBreast Exam	which is a breast lesion documentation system	Not regulated	12/9/2016
127	Import/Misc./78/2016-DC	The Assistant Drugs Controller (I), room No. 10, International Air-Cargo-Complex, Sahar, andheri, Mumbai-400099	Radiopharmaceuticals / Radio-Immuno assays kits		regulated	12/9/2016
128	29/misc/03/2015-DC(30) (A)	M/s. Gale Overseas Trading Pvt. Ltd., Gale House, 5NH/87, NIT, Faridabad-121001	Quease EASE	is indicated for the tratment of chemotherapy induced nausea and vomiting and administered through inhalation	regulated	15-9-2016
129	29/misc/03/2015-DC(221)	M/s. Accredited consultants Pvt LTd., d-29, 1st floor, Acharya Niketan mayur Vihar, Phase-I, Delhi-91	Bite Registration Materials and impression materials	used for dental impression	Not regulated	15-09-2016
130	29/misc/03/2015-DC(242)	Shri S K Bhandari, Brig. DDCDS (E & S), Dte. Gen of Dental Services, Adjutant General's Branch IHQ of MoD (Army), L Block, new Delhi - 110002	COE-PAK Automix -Periodontal dressing	is a two component material for wound dressing to cover stitches or to stabilize loose teeth. Wound dressings	regulated	19-09-2016

131	29/misc/03/2015-DC(261)	M/s. BSN Medical Pvt. Ltd., B-10, Lotus Park, Jai Coach Junction, Opp. Raheja Ridgewood, Jogeshwari (East) Mumbai-400063	JOBST Compri2 and JOBST Compri2 Lite	intended for compression treatment of venous leg ulcers and any accompanying oedemas and the copression treatment of lymphatic oedemas	regulated	26-09-2016
132	29/misc/03/2016-DC(09)	M/s. Dhiti Biotech (india) Pvt. Ltd., Mr. Anand sekhari, c-59/1, okhla Industrial Area, Phase -II, New Delhi-110020	Disposable infusion pumps	consisting of reservoir, PVC tubing, ABS Tubing connector, which is a sterile disposable single use device intended for administration of analgesic in therapy of chronic pains to the patients	regulated	26-09-2016
133	29/misc/03/2016-DC(83)	all port offices of cdsc	Trocars	Trocars are regulated under the "Catheters"	regulated	26-09-2016
134	29/misc/03/2016-DC(257)	Alleen Clinical Research Services, Dr. Sudhakar Bangera, G-5 Mount Meru Road No. 5, Banjara Hills, Hyderabad-500034	CoAg Stop Bleeding Topical Hemostat powder and foam	intended for use as topical dressings for the management of bleeding wounds	regulated	26-09-2016
135	29/misc/03/2016-DC(138)	M/s. Halyard Health India Pvt. Ltd., World Trade Centre, Tower-1, Unit-308, Kharadi, Pune - 411014	Halyard connection tubing with suction valve	intended for removal of oral and nasal secretion from mouth and nose	regulated	27-09-2016
136	29/misc/03/2016-DC(245)	M/s. ConvaTech India Pvt. Ltd., S-604, 6th Floor, World Trade Centre, Brigade Gateway, Yshwantpur, Bengaluru -560055	"Abviser Autovalve" consisting of syringe and infusion tube	used fro monitoring intra-abdominal pressure (IAP)	regulated	13-10-2016
137	29/misc/03/2016-DC(128)	M/s. ConvaTech India Pvt. Ltd., S-604, 6th Floor, World Trade Centre, Brigade Gateway, Yshwantpur, Bengaluru -560055	Ostomy bags and wafers	used for collection of waste from surgical dicerted biological system (colon, ileum, urinary) and certain of stoma	Not regulated	13-10-2016
138	29/misc/03/2016-DC(75)	M/s. ACE Cardiopathy solutions pvt. Ltd., 704, 7th Floor, Krishna Apra Business Square, neta Ji Subhash Palace, Delhi-110034	Comfort-In™ (Needle-Free & Easy-quick Injection System)" contains syringes and adapter	used to deliver 0.5 ml volumes of various medications (especially insulin) and vaccines subcutaneously	regulated	13-10-2016
139	29/misc/03/2016-DC(232)	M/s. Ventura Business Solutions, 109/13/First Floor, Amritpuri-B, Opp Iskon Temple, East of Kailash, New Delhi-110065	(A) G-EYE Endoscopy consisting of G-EYE Balloon Kit & NaviAid Spark/Spark2C inflation or deflation unit (B) NaviAid AB & ABC Balloon	(A) intended for increased diagnostic yield durign colonoscopy, endoscope stabilization during therapy and extended operation range in the colon, small bowel and entire GI tract (B) intended for deep ileoscopy / upper enteroscopy and colonoscopy	(A) not regulated (B) regulated	14-10-2016
140	29/misc/03/2016-DC(285)	M/s. Kanam Latex Industries Pvt. Ltd., Ooppoottil Building, K.K. Road, Kottayam-686001	Surgical Sterile Gloves / Non Sterile Surgical Gloves and medical examination gloves		not covered under the provisions of D7C act	19-10-2016

141	29/misc/03/2016-DC(08) Part III	The Additional Commissioner, Air Cargo Complex, Office of the principal commissioner of customs, new custom house, Meenambakkam, Chennai-600027	"Disposable Hypodermic Needles" are notified as drugs vide G.S.R. 356 (E) dt. 17-03-1989 under the clause (IV) of sub-section (b) of section 3 of the D & C Act	it is clarified that any device which is :- 1. disposable after its first use and 2. penetrate through th hypodermis (The innermost and thickest layer of the skin) for its operation and 3. intended for the purpose of injecting fluids into, or withdraw fluids from, parts of the body The device , bone marrow harvest needle is a single-use harvesting needle comprised of a stainless steel cannula with a molded plastic handle and a stainless steel stylet with a molded plastic handle. it is designed for allogenic and autologous bone marrow harvesting transplantation procedures. It is places through the skin into the marrow cavity, where stem cells and blood are aspirated.	regulated	19-10-2016
142	29/misc/03/2016-DC(150)	M/s. Zuventus Healthcare Ltd., T-184, M.I.D.C., Bhosari Pune-411026, india	Moco-peg	intended as an oral gardle for management of dry mouth i.e. in xerostomia which occurs after radiation and chemotherapy in cancer patients	regulated	25-10-2016
143	29/misc/03/2016-DC(254)	M/s. Lotus Surgical Pvt. Ltd., Khasra No. 105/1 & 2, Twin Industrial Estate, Selaqui, Dehradun-248197	single use Hemorrhoidal stapler	used in hemorrhoids and suturing of intrarectal invaginate	regulated	25-10-2016
144	29/misc/03/2016-DC(255)	The Assistant Drugs Controller (I), Jawaharlal Nehru Port Trust CFS (Imports), Nava Sheva, Navi Mumbai-400707	PU Iodine incise drape	used for string adhesion and continuous broad spectrum antimicrobial activity at the surgical site	regulated	25-10-2016
145	29/misc/03/2016-DC(276)	M/s. Nice Enterprises, New No. 21 (Old No. 12) S1, Rajeshwari Street, Mehtanagar, Chennai-600029	(a) PU Iodine incise drape (b) PTFE Coated Non Stick Tip Cautery Pencil	(a) used for string adhesion and continuous broad spectrum antimicrobial activity at the surgical site (b) indicated to remove tissue and control bleedign by use of high frequency electric current during electrosurgical process	(a) regulated (b) non regulated	25-10-2016
146	29/misc/03/2016-DC(208)	M/s. Unor Exim Pvt. Ltd., 403, Kirti Mahal Building, 19, Rajendra Place New Delhi_110008	Glycosorb@-ABO Column	intended for the specific reduction of anti-A, anti-B and both anti_A and anti-B antibodies, respectively, in plasma to facilitate transplants across the blood group barrier is regulated	regulated	7/11/2016
147	29/misc/03/2016-DC(282)	M/s. Meril Endosurgery Pvt. Ltd., Survey No. 135/2/B, & 174/2, 3rd Floor, , E1-E3, Meril Park, muktanand Marg, Chala, Vapi, Dist. Valsad - 396191	Mesh Fixation Device	Intended for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair	regulated	7/11/2016
148	29/misc/03/2016-DC(253)	M/s. Hetero Healthcare Ltd., Sy. No. 80-8, Melange Tower, 4th floor, C wing, Patrikanagar, Madhavpur, hyderabad, Telengana	mix.jet	(integrated transfer device for drug reconstitution and injection)	regulated	7/11/2016
149	29/misc/03/2016-DC(287)	M/s. Essintra Life LLP, No. 32/2, Soundra Rajan Street, T. Nagar, Chennai-600017, Tamil Nadu	Organ Preservative solution - Eurocollins A & Eurollins B, Servator HTK, Servator C, Servator P, Servator B, and Servator B Plus	used for flushing and cold storage of organs like heart, Lungs, Kidney, liver and pancreas at the time of removal from donor in preparaton for storage, transportation and eventual transplantation in to the recipient are not notified	Not regulated	7/11/2016
150	29/misc/03/2016-DC(243)	M/s. Aramex Trading Co., 9 - Ashok Nagar, Lucknow- 226001	a) Pericem (Dental cement without Eugenol) b) Hydcal	a) act as physical barrier to the healing tissues at the surgical site b) used in pulp capping and as protective liner	a) regulated b) not regulated	16-11-2016

151	29/misc/03/2016-DC(304)	M/s. Goldwin Medicare Ltd., 101/102 vailankanni towers, A wing, Mari Nagar Off., Senapati Bapat Marg, Mahim (W), Mumbai - 400016	Transcutaneous electrical nerve stimulation device, magnetic field therapy device viz., pro sport, best Rsi, Best Pro 1, Ezzi Lift	inteded for symptomatic relief and management of chronic , intractable pain, and adjunctive treatment in the management of post surgical and post traumatic pain	Not regulated	29-11-2016
152	29/misc/03/2016-DC(285)	M/s. Kanam Latex Industries Pvt. Ltd., Ooppoottil Building, K.K. Road, Kottayam-686001	Surgical Sterile Gloves / Non Sterile Surgical Gloves and medical examination gloves	nil	Not regulated	29-11-2016
153	29/misc/03/2016-DC(311)	M/s. Daewoong Pharmaceutical (India) Pvt. Ltd., Plot No. 5A, APIC, IE Prashanth Nagar, Kukatpally, Hyderabad - 500072	eKare insight	a camera system for capture of wound images and estimate of wound dimensions	Not regulated	29-11-2016

2017 Database						
S. NO.	File . No.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	29/Misc/03/2016-DC (333)	M/s Lotus Surgicals Pvt.ltd., Khasra No.1051/1 &2, Twin Industrial Estate, Selaqui, Dehradun-248197	Single use Titanium Ligating Clip	To be used as litigation of vessels or to mark specific surgical site which would show up on the X-Ray later	Regulated	1/2/2017
2	29/Misc/03/2016-DC (316)	Veena Moktail, M/s Periwinkle Technologies Pvt.Ltd., 100,NCL Innovation Park,Pashan,Pune-411008	Digital transvaginal colposcope device	to capture and or video of the cervical region on a n andriod device using a transvaginal pencil camera with inbuilt illumination and autofocus,connected to the anriod device via a micro-US port	Not Regulated	1/2/2017
3	29/Misc/03/2016-DC (331)	M/s Spark Peripheral Technologies, R-2/60,New Raj Nagar, Ghaziabad-201002,UP	HMT Tubing Set	autologous blood transfusion or blood product, fluid or gas via an extracorporeal circuit during surgery or interventional treatment	Regulated	1/2/2017
4	29/Misc/03/2016-DC (327)	M/s Datt Mediproducts Pvt.ltd., 56,Community Centre, East of Kailash,New Delhi-110065	Velnez	Space occpying dressing, prevents cavity of surgery or trauma patients	Regulated	1/2/2017
			Velseal-TG	haemostatic dressing for use in surgical surgeries when control of bleeding by ligature, cautery or other conventional methods are ineffective or impractical		
5	29/Misc/03/2016-DC (328)	M/s Katara Dental, D-10/3,Okhla Industrial Area,Phase-1,Ground floor, New Delhi-110020	Bone Regeneration material i.e.MineralOss Cortical and Cancellous Chips,MinerOss XP, Alloderm and Memlok	To be used as a graft material or graft covering membrane for tissue augmentation or growth of natural bone in dental implants placement	Regulated	1/2/2017
6	29/Misc/03/2016-DC (318)	Dr.N.Sujatha, Associate Professor, Dept.of Applied Mechanics,Indian Institute of Technology, IIT Madras,Chennai-600036	Dual Mode Optical Spectral Analysis System and Laser Doppler Blood Flow Meter	To investigate change in collagen content, skin thickness and microvascularity in diffuse systemic scleroderma patients	Not Regulated	1/2/2017
7	29/Misc/03/2016-DC (321)	M/s Think I,C-101,1st Floor, Sector-2,Noida-201301,UP.	Alogirithm(software)	Bosch Mobile Non -mydriatic fundus camera to diagnose diabetic retinopathy using undus images	Not Regulated	1/2/2017

8	29/Misc/03/2016-DC (286)	M/s Instas Life Science Consultancy Pvt.ltd., 3,Green Park, Opp.Yugalkunj Society, B/H Prabhpark society, naroda, ahmedabad-382330,Gujarat,India	Celsior	Flushing and cold storage of organs, at the time of their removal from the donor, during storage, transportation and transplantation into the recipient	Not Regulated	1/2/2017
9	29/Misc/03/2016-DC (322)	M/s Cybernoid Healthcare Pvt.Ltd., Plot No.70,1st Layout, Teachers Colony, Kolathur,Cehnnai-600099	Cybo Limb	Rehabilitating spinal cord injury patients with lower limb neurological motor deficit	Not Regulated	1/2/2017
10	29/Misc/03/2016-DC (346)	M/s Consumer Marketing (I) Pvt.Ltd., 201,Dhantak Plaza, Makwana Road, Marol, Andheri (East),Mumbai	Liquid Bandage	Prevention of infection by limiting exposure to dirt and germs in case of minor cuts, abrasions and blisters	Regulated	1/10/2017
11	29/Misc/03/2016-DC (284)	M/s Terumo Penpol Pvt.ltd., P.B.No.1605,I-2,Jawahar Nagar,Thriuvananthapuram-695003,Kerala,India	Imugard III-RC	used for removing leukocytes from blood or red cell component to collect or transfuse leukocyte poor red cells in the preparation of transfusion red blood cells	Regulated	1/10/2017
			Imugard III-PL	Used for removing leukocytes from platelets component to collect or transfuse leukocyte poor red cells in the preparation of transfusion platelets		
12	29/Misc/03/2016-DC (157)	M/s MOD Medicare Systems Pvt.Ltd., GH-2/81-B,Paschim Vihar, New Delhi-110063	Bag Spike with Check Valve	safe and easy transfer of liquid drug from and into bag/bottle as a part of or through syringes before administration to the patients	Regulated	1/10/2017
			Bag Spike			
			Smartsite needle free valve			
13	29/Misc/03/2016-DC (344)	M/s Genetix Biotech Asia Pvt.ltd., 71/1,1st floor, Shivaji Marg, Najahfarg Road, New Delhi-110015	Antipacth	to be used in therapy (an electromagnetic pulse therapy) for chronic and acute pain due to muscle and joint soreness, strains and sprains, arthritis, fibromyalgia	Not Notified	1/24/2017
			Anti Static space chamber and silicon facial mask	deliver medication more effectively to the lungs compared to pMDI alone, enabling asthma and COPD Patients to take control		
			Paingone	To provide pain relief by usage of a low frequency electrical charge produced by crystals		

14	29/Misc/03/2016-DC (304)	M/s Goldwin Medicare Ltd., 101/102,Vailankanni Towers, A Wing, Mari Nagar, Off.Senapati Bapat Marg,Mahim (W),Mumbai-400016	Surgical dressing both active and inactive		Regulated	2/14/2017
15	29/Misc/03/2016-DC (350)	M/s Hansraj Nayyar Medical India, L8 Laxmi Industrial Estate, Link Road, Oshiwara,Andheri (W),Mumbai-400053	Vented Intubating introducer	airway management	Regulated	2/14/2017
16	29/Misc/03/2016-DC (351)	M/s ResMed India Pvt.Ltd., Unit No.205,2nd floor, Southern Park,D- 2,District Centre,Saket, New Delhi- 110017	Nasal Cannula	Used to deliver supplemental oxgen or increased airflow to a patient or person in need of respiratory help	Not Regulated	2/14/2017
17	29/Misc/03/2016-DC (196)	M/s Khandelwal Laboratories Pvt.ltd., 78/87,Dattaram Lad Path,Mumbai- 400033,Maharashtra,India	TruScreen Ultra Cervical Screening System	Used in cervical cancer screening by providing a direct means of tissue differentiation as a primary screening tool in the general population	Not Regulated	2/14/2017
18	29/Misc/03/2015-DC (204)	M/s Vygon India Pvt.Ltd., B-17,Infocity, Section-34,Gurgaon-122001(Haryana)	Gravity Set	Used a s connection tube between feeding tube and feeding bag	Not Regulated	2/28/2017
19	29/Misc/03/2016-DC (340)	M/s Inmito Meditech Pvt.ltd., 216-A, Humyan Pur, Safdarjung Enclave, New Delhi-110029	Spiegelberg probes viz.true tunneling intraventricular probe 7F & 9F, silverline ventricular probe 8F, Silverline Ventricular probe with cranial bolt 8F, Silverline Ventricular probe 10F, Probe 3N, Probe 3NXL, Probe 3DL and Probe DLXL	mointoring intracranial pressure measurement and drainage of cerebrospinal fluids	Regulated	2/28/2017
	29/Misc/03/2017	M/s Morulaa Healthtech Pvt.ltd., Plot No.28 1st Floor, Rajeshwari Street	Ten20 Conductive Paste	Used as an adhesive to hold non - disposable electoneurodiagnostic electrodes in place on intact skin sites		

20	29/Misc/03/2017-DC (23)	No.38,1st Floor, Rajeshwari Street, Santhosh Nagar,Khandanchavdi,Chennai-96	Nuprep Gel	To reduce the impedance of the skin to local potential differentials as measured by electroneurodiagnostic and electrocardodiagnostic equipment	Not Notified	2/28/2017
21	29/Misc/03/2017-DC (22)	M/s Datt Mediproducts Pvt.ltd., 56,Community Centre, East of Kailash,New Delhi-110065	Velseal-TG	haemostatic dressing for use in surgical surgeries when control of bleeding by ligature, cautery or other conventional methods are ineffective or impractical	Regulated	2/28/2017
			Velnez	act as a space occupying dressing, preventing adhesion by separating the ocmpromised muscosal surfaces and also,helping in healing and achieving homeostasis in patients undergoing nasal/sinus surgery		
22	29/Misc/03/2017-DC (19)	M/s Rithwik Pharma Pvt.ltd., Plot No.11-13-1160/406,Ramprathap Niwas, Green Hills Colony (Moyya Nagar), Near Asthalaxmi Arch., L.B.Nagar, Hyderabad,Telangana-500102	CES UltraTM-Cranial Electrotherapy Stimulator	treatment of insomnia, depression or anxiety	Not Regulated	3/15/2017
23	29/Misc/03/2017-DC (24)	M/s Innovee ,A-401, Selarka Sadan, M.P.Vaidya Marg, Off.Tilak Road, Ghatkopar (East),Mumbai-400077	Neal Cast Casting Type	Use in the construction of most common orthopedic casts, as well as specialized orthotics and prosthetics devices	Regulated	3/15/2017
24	29/Misc/03/2016-DC (345)	M/s Morulaa Healthtech Pvt.ltd., Plot No.38,1st Floor, Rajeshwari Street, Santhosh Nagar,Khandanchavdi,Chennai-96	Avacen 100,A head therapy	temporary relief of minor muscle and joint pain and stiffness: the remporary relief of joint pain associated with arthritis:muscle spasms, minor strains and sprains, muscular relaxation and the temporary increase of locak circulation where applied	Not Notified	3/15/2017
25	29/Misc/03/2016-DC (315)	M/s HLL lifecare Limited, HLL Bhavan, Poojappura,P.O.Thiruvananthpuram-695012	Skin Stapler	Nil	Regulated	3/22/2017

26	29/Misc/03/2017-DC (13)	M/s India Medtronic Pvt.Ltd., 1241,Solitaire Corporate Park, Building No.12,4th floor, Andheri -Ghatkopar Link Road, Andheri (East),Mumbai- 400093,India	Dialysate purification sorbernt cartidge module	Used as a filter/purifier to remove toxins extracted from the body present in the used dialysate and then balances the ionic concentration of the purified dialysate	Not Regulated	3/22/2017
27	29/Misc/03/2017-DC (36)	M/s Vivyan Life Sciences Pvt.Ltd., Corp.Off:-B-91,Flatted Factory complex, Okhla Industrial area, phase-III,New Delhi- 110020	Blood Lancet/Laser Lancet	Used to get blood by perforating fingure tip skin of patient by using single pulsed laser	Not Regulated	3/22/2017
28	29/Misc/03/2017-DC (12)	M/s Emergo India Consulting Pvt.Ltd.,8/1,1st floor, Vasavi Colony, Kakguda, Near Pciket, Secunderabad,Hyderabad-Cir-2,Telangana- 500015	Single use Biopsy Forceps	Used for endoscopic histological sampling of various tissue sites within the gastrointestinal and bronchial tracts via the operating channel of endoscopic instruments	Regulated	3/30/2017
29	29/Misc/03/2017-DC (58)	M/s Truskin Gloves Pvt.ltd., Plot No.14- C,Cochin SEZ, Kakkanad,Cochin- 682037,kerala,India	Sterile Surgical Gloves	Nil	Not Regulated	4/5/2017
30	29/Misc/03/2017-DC (50)	M/s MTEX (I) Pvt.Ltd.,A-26/4,Mohan Co- Operative Industrial Estate,Mathura Road, New Delhi-110044	Rehabilitation brace with BOA Technology	Used in Joint disorders, pre-post- surgical treatment	Not Notified	4/5/2017
			Nebulizer	used in the treatment of lower sirways respiratory diseases like asthma		
31	29/Misc/03/2016-DC (353)	Dr.Rakesh Tulli, J C Bose National Fellow and Sr Research Advisor, Univeristy Institute of Engineering and Technology, Sector-25,Punjab University, Chandigarh- 160014	Dental Aligners	Use in the orthodontic treatment for teeth alignment	Not Regulated	4/5/2017
32	29/Misc/03/2017-DC (46)	M/s Fostril (I) Pvt.Ltd., G-36,outer CIRCLE, CP,New Delhi-110001	Dust Filters	Used to protect from dust and wood splinters from entering the nose	Not Regulated	4/5/2017
33	29/Misc/03/2017-DC (37)	M/s Medprime Technologies Pvt.Ltd., CM- 03,3rd floor, CSRE Bulding, IIT Bombay, Powai, Mumbai-400076,maharashtra,India	Infuchek	Used to check an ongoing infusion after desired volume of fluid has been infused and gives an audio alert for the same	Not Regulated	4/5/2017
			Cillika Microscope	Used to help laboratory medicine professional to make a diagnosis through a portable digital platform		

34	29/Misc/03/2017-DC (38)	M/s Brainrootz Labs Pvt.Ltd., 10-J, Gopala tower, rajendra place,new delhi-10008	Electrochemptherapy	Getting chemotherapy into cancer cells using an electric pluse to send the chemotherapy in to cancer cells-electroporation	Not Regulated	4/5/2017
			Combined Antineoplastic Thermotherapy bladder recirculation system (Combat BRS V4 System)	Treatment for the treatment of cancerous cells by using thermal energy		
35	29/Misc/03/2016-DC(262)	M/s Myovatec Surgical System Pvt.Ltd., A-12/42A,MIG DDA Flats, Kalkaji Extension,New Delhi-110019	GEM Mircovascular Anastomotic Coupler device and system	uSed in the anastomosis of veins and asteries normally encountered in microsurgical procedures only in the peripheral vascular system	Not Notified	4/5/2017
36	29/Misc/03/2017-DC (55)	M/s General Medical Systems Pvt.Ltd., Navdeep Industries Compound, Near Old iNcome tax office, flood defence bandh, sirhind-140406,Punjab	Piles GMS Relief Device	Used to get relief from swelling, pain and irritation in patients suffering from piles	Not Notified	4/11/2017
37	29/Misc/03/2017-DC (60)	M/s Synergy Pharma Formulations India Pvt.Ltd., 1003,Meadows, Sahar Plaza Complex,J.B.Nagar,Andheri-400059	Esoxx	Used as a topical agent in treatment of esophageal and gastric lesions and to imporve symptoms of GERD or gastritis	Regulated	4/11/2017
38	29/Misc/03/2017-DC (21)	M/s Sri Research for Tissue Engineering Pvt.Ltd., Sri Shankar Research Centre, Rangadore Memorial Hospital,1st Cross, Shankarpuram,Bangalore-560004,India	Devitalized amniotic membrane derived from human placenta	Used to heal superficial ulcers	Regulated	4/18/2017
			Sponge made with devitalized human amnitoic and chorion membrane and gelatin	Used to heal drop ulcers in conjunction with negative wound pressure therapy		
39	29/Misc/03/2017-DC (73)	M/s Parazelus India Pvt.Ltd.,802,Thaneone,DIL Complex, Behind Cinewonder Mall,Majiwada, Thane West,Mumbai-400610,Maharashtra	Heckle HT3000,an infrared whole-body hyperthermia device	Used for regenerative processess of body,muscle relaxation	Not Notified	4/24/2017
			Hydrosun 750 or 575 an infrared heat treatment device	Used in treatment of degenerative rhematic illness, chronic neuritis, spine disorders		
40	29/Misc/03/2017-DC (79)	M/s India Health Link Pvt.Ltd., SCO#394,New Grain Market, Karna,Haryana,India	Health Kisok	Used to measure blood pressure, heart rate pulse, weight, body mass index, body mass composition ,ECG	Not Regulated	4/24/2017

41	29/Misc/03/2017-DC (98)	M/s Romsons Scientific & Surgical Industries Pvt.Ltd., 63-64.Industrial Estate, Nunhai Agra-282006 (India)	Resuscitator bag	Used to inflate the lungs of an unconscious person is not breathing using positive pressure, in order to keep them oxygenated and alive	Not Notified	5/23/2017
42	29/Misc/03/2017-DC (68)	M/s Accredited Consultants Pvt.Ltd., D-29,1st floor, Acharya Niketan,Mayur Vihar-1,Delhi-110091	Prepex	Circumferential excision of the foreskin or prepuce at or near the level of coronary sulcus	Not Regulated	5/23/2017
43	29/Misc/03/2017-DC (75)	M/s Siddhi Vinayak Enterprises, 11/343,Geeta Colony,Delhi-110031	New Wings Pain relief patch	To get relief from low back pain, burises, sprains, stiff neck, joint pain, muscle pain, frostbite	Regulated	5/23/2017
44	29/Misc/03/2017-DC (99)	M/s Morulaa Healthtech Pvt.ltd., Plot No.38,1st Floor, Rajeshwari Street, Santhosh Nagar,Khandanchavdi,Chennai-96	MicrO2	Used to be reduce night time snoring and mild to moderate obstructive sleep apnear (OSA) in adults	Not Notified	5/23/2017
45	29/Misc/03/2017-DC (111)	M/s IDS Denmed Pvt.Ltd., A-23/3,Ground floor, Mayapuri Industrial Area Phase-1,New Delhi-110064,India	Clinical Disinfectants,Wipes	Used for disinfection/dedorization and cleaning of Medical Device surface	Regulated	5/23/2017
46	29/Misc/03/2017-DC (49)	M/s Alaric Arooojis, Medical Director, CURE Clubfoot Maharashtra,B.J.Wadia Hospita, Acharya Donde Marg,Parel,Mumbai-400012	Miracle Feet Foot Abduction Brace	Pilot study in the treatment of idiopathic Clubfoot	Not Notified	23-05-2017
47	29/Misc/03/2017-DC (104)	M/s Innaumation Medical Devices, #1/1-17,1st cross, KB Temple,6th Block, Rajajinagar, Banagalore-560010,Karnataka,India	Aum Voice Prosthesis (Internal replacement prosthesis)	Used as a mechanical speaking device, to help patients of throat cancer who have lost their voice after surgical removal of voice box	Regulated	5/23/2017
48	29/Misc/03/2017-DC (107)	P & A Law Offices, 1st floor, Dr.Gopal Das Bhawan 28, Barakhamba Road,New Delhi-110001,India	Medical socks	To prevent or cure deep vein thrombosis	Not Regulated	5/30/2017
			Compression Socks	to encourage blood circulation in the limbs by applying pressure along the muscles		
			Deodrant Socks	To reduce stiffness and odor of the feet		
			Thermo Socks	To keep soles, Legs and Feet warm		
			Socks with sole support	To reduce inflammation of the arch of foot		
			Socks to prevent falling	To prevent falling and twisting of ankles		

49	29/Misc/03/2017-DC (106)	M/s Nano Therapeutics Pvt.Ltd., D-54/2,Hojiwala Industrial Estate,Sachin Surat,Gujarat-394230	Quantacore HD Endobronchial Ultrasound Transbronchial Aspiration Needle (EBUS-TBNA)	Endobronchial ultrasound endoscopes for ultrasound guided fine needle aspiration of the submucosal masses,lymph nodes and intraperitoneal masses of the tracheobronchial tree and gastrointestinal tract	Regulated	6/13/2017
50	29/Misc/03/2017-DC (120)	M/s KCI Medical India Pvt.Ltd., No.1,Ramchandra Complex, 1st floor, 1st cross, M.S.Nagar, Opp.Ayyapa Temple, Bangaluru-560038,Karnataka,Indi	Adaptic Digit Non Adhering Digit Dressing	a range of mild to severe digit injuries	Regulated	6/13/2017
51	29/Misc/03/2017-DC (121)	M/s Sunheri Marketing Pvt.ltd., Shri Ram Marg,Huda Bypass,Sector-12,Opposite Indo Spinning Mills,Panipat-132103,Haryana,India	Contactless Infrared Thermometer	To measure the temperature of various surfaces, liquids and body	Not Notified	7/11/2017
			Piston Type Nebulizer	To make smooth breath and to trasnform liquid medicines into fines easy to inhale for kids		
			Digital Blood Pressure Machine	To measure the blood pressure of human body		
			Electronic Breat Pump	To smoothen the flow of mother milk from breast		
			Nasal Aspirator or Nose Cleaner	To clean nose of infants		
52	29/Misc/03/2017-DC (132)	M/s Medishare Ltd.,S-439,G.K.Part-1,New Delhi-110048	TEN 20,A conductive Gel	To use as an adhesive to hold EEG Electrodes in place on intact sites	Not Notified	7/11/2017
53	29/Misc/03/2017-DC (100)	M/s Delvin Surgicals Pvt.ltd., New No.25,12th Cross,Shastri Nagar,Adyar,Chennai-600020	Disposable Hemoperfusion Cartidges (models:HA130,HA230,HA280,HA330,HA330 II.BS330 & DNA230)	Treatment of specific intoxication	Regulated	7/11/2017
54	29/Misc/03/2017-DC (141)	M/s Bryogen Pharmaceuticals Pvt.ltd., 8H Gopala, Tower, Rajendra Place, New Delhi-110008	Farmactive Silver Spray	Topic and temporary treatment to not infected skin lesions(eg.cuts, abrasions, wounds, minor llocalized burns, postoperative wounds, decubitus, ulcers, incontinence irritations or diapers irritation)	Attracts definition of Drugs	7/11/2017

55	29/Misc/03/2017-DC (156)	M/s Becton Dickinson India Pvt.ltd., Head Office:-5th and 6th floor, Signature Tower B, South City 1,Gurgaon-122001,Haryana	Extension Tubing Assemble of the product Venflon 2.0	To transfer medication to the catheter and provide multiple port access for connectors with secondary flashback by releasing the air only	Regulated	7/18/2017
56	29/Misc/03/2017-DC (136)	M/s Terumo India Pvt.ltd., 1601 & 1602,Tower-B,16th floor, Unitect Cyber Park,Sector-39,Gurgaon-122001,Haryana	Terumo Oral and Eternal Syringes	To use for oral and enteral administration of liquid medication/nutrition and for flusing of enteral feeding lines and aspiration of stoamch fluid (during palcemnt of enteral feeding system)	Not Notified	7/18/2017
57	29/Misc/03/2017-DC (160)	M/s Swastik Enterprises, 126-127,Hapa Indurtial Area, Jamnagar-361120,Gujarat,India	Brand Rfid Microchip Applicator	To inject a mircochip into an animal for its identification and tracking purpose	Not Notified	7/25/2017
58	29/Misc/03/2017-DC (149)	M/s LiNA Medical India Pvt.Ltd.,702,Madhuban Building, 55,Nehru Place,New Delhi-110019	1.LiNA Port 2.LiNA FleXealTM 10 3.LiNA FleXealTM 5 1.LiNA Power blade 2.LiNA Lapscissors 3.LiNA Electrodes (blade electrodes-coated,blade electrode coated and insulated, blade electrode) 4.LiNA Pencils (LiNA Surgipen) 5.LiNA SeaStar TM and LiNA Skin HookTM 6.LiNA EndoHookTM 7.LiNA AntiFod SolutionTM (LiNA elfrod LiNA Clear Sight and	Sterile and single use devices used for making the port entry in abdominal cavity Surgical equipments	Regulated Not regulated	25-07-2017
59	29/Misc/03/2017-DC (149)	M/s Teleflex Medical Pvt.Ltd., Old No.10,No.19,1st floor and Ground floor, Harrington Road,Chetpet-600031,Chennai,India	Asherman Chest Seal	Treatment of pneumothorax and preventing pneumothorax tension from stab or gunshot wound	Regulated	8/1/2017

60	29/Misc/03/2017-DC (155)	M/s Cipla Ltd., Regd Office Cipla House, Peninsula Business Park, Ganapatro Kadam Marg, Lower Parel, Mumbai	Medication free dry powder inhaler	To delivers the medication to the lungs in the form of a dry powder	Not Notified	8/1/2017
61	29/Misc/03/2017-DC (88)	M/s Sen Brothers Pvt.Ltd., 22,R.N.Mukherjee Road, 5th floor, Kolkata-700001,India	TU Master Line F-Grip self filling dose reusable syringes	Vaccination of Alvan. Bovine, canine,feline	Not Notified	8/7/2017
62	29/Misc/03/2017-DC (184)	M/s Dialec Medical Services Pvt.Ltd.,Plot No.311,Survey No.197, Block GA, 1st floor,1st cross,karnataka-560038,	Citra-Lock solution	Prevent catheter related to bacteremia and clotting	Regulated	8/17/2017
63	29/Misc/03/2017-DC (140)	Dr.V.S.Venkatesan,Professor-Biomedical Engineering,TMA Pai Chair in Medical Devices, Manipal Institute of Technology, Manipal-576104,Karnataka,India	Artificial Kidney-Dialysis Cartidge	In removal of urea, creatinine and other unwanted material takes place across the membrane from the blood	Not Regulated	8/17/2017
64	29/Misc/03/2017-DC (164)	Dr.Shreemoyee De,International Oncology Services Pvt.Ltd., Fortis Hospital,Sector-62,Noida	Mobile ODT	to be used as a smart phone based cervical imaging in cervical cancer screening program	Not Notified	8/17/2017
			Zilico (electrical impedence spectrograph devices)	Detecting cervical cancer		
65	29/Misc/03/2017-DC (103)	M/s Oxycan Solutions Pvt.Ltd., 42 A/B, Yogi Nagar Township, B/S Zenith Tins, N.H.-8,Channai-391740,Vadodara	95% pure oxygen with and without flavor	All natural and perfect alternative to the energy drinks, shots and supplements	Notified	8/29/2017
66	29/Misc/03/2017-DC (206)	M/s Koye Pharmaceuticals Pvt.ltd., Regd Office:-7,The Centrium,Phoenix Market City, LBS Marg, Krla (West)-400070,Mumbai-400070	Jetx-ND/Jetforce	Cleansing and debridement of wounds and in treating diabetic ulcers,pressure ulcers,venous stasis ulcers and burns	Regulated	9/12/2017
67	29/Misc/03/2017-DC (148)	M/s Geneagles Global Health City, #439,Cheran Nagar, Sholinganallur,Medavakkam Road, Perumbakkam,Chennai-600100,Tamil Nadu	TransMedics Organ Care System	Used for the flushing and cold storage of organs like heart, lung, kidneys, liver and panceras at the time of removal from donor in preparation for storage,transportation and eventual transplantation in to recipient	Not Notified/Regulated	9/12/2017

68	29/Misc/03/2017-DC (212)	M/s Generix Life Sciences Pvt.Ltd., Unit No.4,5 & 6,207, 3rd floor, Shahpur Jat-110049,New Delhi	Perinel U & Perinel Rehab, a remote Controlled incontinence stimulator	Treatment of stress incontinence, urge incontinence and mixed incontinence	Not Notified	9/19/2017
69	29/Misc/03/2016-DC (131)	M/s Duraent Lifesciences LLP, 1-98/9/12A,2nd floor, T & A Plaza, Jain Enclave, Hyderabad-500081	(Servator P,Servator C, Servator B, Servator B+,Histidine-Tryptophan-Ketoglutarate (HTK),Eurocollins A+B, Belezer UW Cold storage solution,penta starch solution	Used for theflushing, ex vivo cells,cold storage or organs like heart,lungs, kidneys, liver and pancreas at the time of removal from donor in preparation for storage, transporation and eventual transplantation in to recipient	Not Notified	9/26/2017
70	29/Misc/03/2017-DC (158)	M/s Mavinbo Services, A/4, Anjali Society, M.Dmarg, Panchakhandi,Thane (West),Mumbai-400602	Histofreezer protable cryosurgical system	Cyyosurgical treatment for removal of different types of warts and skin tages	Regulated	9/26/2017
71	29/Misc/03/2016-DC (131)	M/s Duraent Lifesciences LLP, 1-98/9/12A,2nd floor, T & A Plaza, Jain Enclave, Hyderabad-500081	Servator C, Servator B+, Histidine-Tryptophan-Ketoglutarate (HTK),Eurocollins A+B, Belezer UW Cold storage Solution, Penta Starch Solution	Used for Flushing, perfusion, hypothermic preservation, component in cryopreservation media for human ex vivo cells, cold storage of organs like heart, lung,kidneys, liver and pancreas at the time of removal from donor in prepartion for storage, transportation and eventual transplantation in to recipient	Not Notified	9/26/2017
72	29/Misc/03/2017-DC (224)	M/s Emergo India Consulting Pvt.Ltd.,8/1,1st floor, Vasavi Colony, Kakguda, Near Pciket, Secunderabad,Hyderabad-Cir-2,Telangana-500015	TransAeris System	Used in prevention and treatment of ventilator-induced diaphragm dysfunction (VIDD)	Not Notified	10/4/2017
73	29/Misc/03/2017-DC (252)	M/s Myovatec Surgical System Pvt.Ltd., A-12/42A,MIG DDA Flats, Kalkaji Extension,New Delhi-110019	Conevita`s silicon Intra gastric ballon with radio opaque catheter	Used to induce precocious satiety sensation in obese patients	Regulated	10/4/2017
74	29/Misc/03/2017-DC (246)	M/s Laerdal Medical India Pvt.Ltd., No.10,1st floor, 1st street, Dr.Subbararayan Nagar,Kodambakkam,Chennai-600024	Upright Oxygen Kit	Used to provide supplement of oxygen through the upright bag mask to the baby	Not Notified	10/4/2017

75	29/Misc/03/2017-DC (43)	M/s Sibre Systems and Services Pvt.Ltd., 39,2nd Main Road, R.A.Puram,Chennai-600028	SB Knife standard type, SB Knife short type and SB Knife Jr.Type	Used for Endoscopic sub mucosal dissection	Regulated	10/10/2017
76	29/Msic/03/2016-DC (304)	M/s Goldwin Medicare Ltd., 101/102,Vailankanni Towers, A Wing, Mari Nagar, Off.Senapati Bapat Marg,Mahim (W),Mumbai-400016	Srugical Dressings		Regulated	10/16/2017
77	29/Misc/03/2017-DC (265)	M/s Troikka Pharmaceuticals Ltd., Pots-Thol, Tal-Kadi, Mehsana-382728,Gujarat,India	Soy Phosphatidylcholine Gel	Pain Relief and improvement of joint function by lubricating damaged cartilage	not notified	10/16/2017
			Polyacrylic Acid Vaginal Gel	Restoration of Vaginal Ph and maintenance of good vaginal health		
78	29/Misc/03/2017-DC (272)	M/s Menz HEALTH International Pvt.Ltd., 67/1,New Rihtak Road, Karol Bagh,new delhi-110005	Boss-2000-2 Vaccum Erection Device	Assisting users in achieving full erection i.e. To create an erection in men with erectile dysfunction by means of an applied vaccum to the penis	Does not fall under the notified categories	11/1/2017
79	29/Misc/035/2017-DC (268)	M/s Borivli Rubber Works, A/3, Mangal Kunj, 1st Floor, S.V.Road, Borivli (West),Mumbai-400092	DEA Cup (Menstrual Cups)	Women during the menstruation time for collecting the uterine lining fluid	Does not fall under the notified categories	11/1/2017
80	29/Misc/03/2017-DC (177)	M/s Tricell Bilogics, Plot No.4 &5, Dhanrajapuram, Kolathur,Chennai-600099	Tricell PRP Kit	Separating a small volume of blood to prepare Platelet/Cell concentrate	Not Notified	11/6/2017
81	29/Misc/03/2017-DC (273)	M/s Prime Medica Promotion Pvt.Ltd., E/96, FIDC MANJUSAR,sSalvi Road, Vadodara-391775	Splint made up of plaster of paris	Temporary immobilization of fractures, sprains or strains in limbs	Regulated	11/6/2017
82	29/Misc/03/2017-DC (301)	M/s Robert Bosch Engineering and Business Solutions Pvt.Ltd., 123,Industrial LAYOUT, Hosur Road, Koramagala,Bangalore-560095	Bosch Eye Cam (non-Mydriatic fundus camera) and algorithm/software	Capturing digital iamges and videos of the fundus/human eye, to be used as artificial intelligence for diabetic retinopathy screening	Does not fall under the notified categories	11/14/2017
83	29/Misc/03/2017-DC (300)	M/s Fashion Identity Pvt.Ltd., 13, Shreepal Complex, SUREN Road, Andheri	Barbicide Concentrate	Disinfectant in hospitals,healthcare establishments	Regulated	11/14/2017
			Clippercide Spray	Disinfection, lubrication, cleaning,cooling and as antirust by haridressers stylists, animal groomers and veterinarians	Regulated	

	DC (300)	East,Mumbai-400093	Ship Shape Professional CLEANER	Cleaning brushes, combs, head,neck and foot sinks, countertops, chairs, caps and aprons	Not Regulated	
			Ship Shape Powder	Institutional dish machine detergents	Not Regulated	
84	29/Misc/03/2017-DC (304)	M/s Woman`s Nature LLP, 95 &96, 1st floor, 21st Main Road, BSK,2nd Stage,Bangalore-560070	Daysy,Pearly and Lady Comp/Lady Comp Basic	It s a hand held electronic fertility indicators for pregnancy prevention and family planning	Not Notified	11/16/2017
85	29/Misc/03/2017-DC (295)	The licensing Authority, Govt of Puducherry,Dept of Drugs Control, Govt Hospital Building, 1st Floor, Murungapakka, Kombakkam-605004	Dr.Thacharodi`s Xenoderm,Dr.Thacharodi Xzenostat,Dr.Thscharodi`s Collagen Dry Sheet, Dr.Thacharodi`s Xenoderm	It is intended as skin/wound dressings	Not "New Drugs"	11/17/2017
86	29/Misc/03/2017-DC (269)	M/s Daewoong Poharmceuticals (india)Pvt.Ltd., Plot No:-5A,APIIC, I.E.Prashnath Nagar,Kukatpaaly,Balanagar	Caretropin pen without caretopin (somatropin) liquid cartridge and	Intended for injecting correct dose injection of somatropin from liquid cartridge by pressing injection button	Not Regulated	12/12/2017
87	29/Misc/03/2017-DC (306)	The Under Secretary,DFQC Section, Ministry of Health and Family Welfare, Nirman Bhawan New Delhi-110011	Orthopedic Implants/equipments		Not Notified	12/18/2017
88	29/Misc/03/2017-DC (228)	Shri R.Nihal Pedric, Deputy Director, National Pharmaceutical Pricing Authority, Dept of Pharmaceuticals,3rs and 5th floor, YMCA Culture Centre Building No.1 Jai Singh Road, New Dlehi	Medical Devices,Catheters and Stents		Notified and Regulated	12/18/2017
89	29/Misc/03/2017-DC (270)	M/s Ayurman Natural Healthcare,1707,Sadashiv Peth, Near Udyan Karyalaya,Pune-411030	Disposable speculam Bio Fluff(ared shaped stem preassembled in ordcer to facilitate the introduction into the anus)	Intended for introduction of water and the draining of excreted	Regulated	12/19/2017
90	29/Misc/03/2017-DC (184)	M/s Dialec Medical Services Pvt.Ltd.,Plot No.311,Survey No.197, Block GA, 1st	Citra Lock solution is claimed to be having anti	Intended to prevent catheter related bacteremia and clotting	Regulated	12/19/2017
91	29/Misc/03/2017-DC (314)	M/s InkosbioPharma, R-775,2nd Floor, New Rajendra Nagar, New Delhi-110060	Electro Impedence Mammograph under the models MEM 20-11 & MEM 20-08	Intended for imaging and diagnostics of pathological changes of the breast tissues	Not Notified	12/19/2017
92	29/Misc/03/2017-DC (326)	M/s Luvia Trading Pvt.Ltd.,#947,JMD Megapolis,Sector-48,Sohanan Road,Gurgaon-122018,Haryana	O-Lens unde rthe models JENITH3,Russian Velvet,Secriss3	to used as contact lens	Not Notified	12/26/2017

93	29/Msic/03/2017-DC (325)	M/s Delta Biosciences Pvt.Ltd.,#1,Saini Complex, Dadu Majra, Chandigarh-160014	Dental Implants instruments ,drills and surgical kits	Used in dental surgery	Not Regulated	12/26/2017
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2018 Database

S. NO.	File . No.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	29/Misc/03/2017-DC (338)	M/s Oralla Dental Private Limited	GIC Inomer Cements	For self curing glass inomer based radiopaque filling cement	Not Regulated	1/1/2018
2	29/Misc/03/2017-DC (340)	M/s Delta Biosciences Pvt.Ltd.	Dental Root Canal Disinfection Kit	For purposes of performing root canals and related dental procedures,by a trained professional in general dentistry	Not Regulated	1/1/2018
3	29/Misc/03/2017-DC (328)	M/s Meril Endo Surgery Pvt.Ltd.	Sterile Surgical Sutures	Nil	Regulated	1/8/2018
4	29/Misc/03/2017-DC (341)	M/s CliniExperts Services (P) Ltd	Infusion Pump	For matching tube or syringe to control the flow rate that is infused into patients	Regulated	1/8/2018
5	29/Misc/03/2018-DC (08)	M/s Orbit Life Sciences Pvt.Ltd.	NovApex N31 Apex Locator	Fro apex localization and working length determination during root canal treatment by dentist	Not Notified	1/8/2018
6	29/Misc/03/2018-DC (21)	M/s Pall India Pvt.Ltd.	1.Pall Ultipor 100 Braething system Filter 2.Pall breathing system filter 3.Pall Pharm Assure 25mm hydrophobic vent filter	For eliminating filters or breathing filters	Not Notified	1/12/2018
7	29/Misc/03/2018-DC (04)	M/s Impluse Dynamics (USA) Inc.	Optimizer Smart-A cardiac contractility modulation system	For treating patients with symptomatic heart failurte due to left ventricular dysfunction by delivering non excitatory cardiac contractility modulation (CCM) electricial signals to right ventricle	Not Regulated	1/12/2018

8	29/Misc/03/2018-DC (17)	M/s Halyard Helath India Pvt.Ltd.	Sterile Drapes	Nil	Regulated	1/12/2018
9	29/Misc/03/2017-DC (329)	M/s Meril Endo Surgery Pvt.Ltd.	Topical Skin Adhesive and Surgical Adhesive	Nil	Nil	1/12/2018
10	29/Misc/03/2017-DC (344)	M/s Meril Life Sciences Pvt.Ltd.	Eustachian Tube Balloon Dilation System	Nil	Nil	1/12/2018
11	29/Misc/03/2017-DC (346)	M/s Ingress India Healthcare Consultants	Woudn Care dressing Spray	For in all sorts of medical facilities, which need to treat surgical closure, wound trauma, skin inflammation,suppurative skin infection and providing first sid treatment of all sorts of wound happended in field operations. sports, military training and outdoor	Regulated	1/15/2018
12	29/Misc/03/2018-DC (10)	M/s Reckitt Benckiser India Pvt.Ltd.	K-Y tm Lubricating jelly	For easy insertion of catheters, scoops, rectal thermometers,enemas,docuhes	Not Notified	1/15/2018
13	29/Misc/03/2018-DC (53)	M/s Air-O -Pure	Air Breath, canned breathing air	Used by officer workers,atheletes, pregnant and breastfeeding women,children,persons having asthma and chronic illness citizens	Not Notified	2/15/2018
14	29/Misc/03/2018-DC (02)	M/s Bion Atrium Medical Care Pvt.Ltd.	1.KIWI Omnicup 9VAC 6000M 2.KIWI Omnicup with traction Force Indicator (VAC 6000MT	Used for foetal vaccum delivery assistance in conditions of 1) Dystoica 2) uterine inertia 3) maternal exhaustion (ineffective voluntary effort) or 4) maternal or foetal distress	Not Regulated	2/15/2018
15	29/Misc/03/2018-DC (56)	M/s Philips India Limited, Plot No.B-79,MIDC, Phase-II,Chakan Taluka,Khad, Village-Savardari,Pune-410601,Maharashtra,India	Interventional and diganostic X Ray equipment	Nil	Not Notified	2/15/2018
16	29/Misc/03/2017-DC (294)	M/s Conect Critical Solution Pvt.Ltd., A 403-404,Sector-47,Sohna Expressway,Gurgaon-122002,Haryana,India	Conetct Sterile Hydrop[ure	Use for sporocidal solution for cleaning/disinfecting hard surfaces coming in contact with the product	Regulated	2/23/2018

17	29/Misc/03/2018-DC (13)	M/s Mylan Pharmaceuticals Pvt.Ltd., Plot No.1-A/2,MIDC, Industrial Area,Taloja, Panvel Raigad (Dost.)-410208,Maharashtra,India	End Warts Pen and End Warts Bottle	Used for removal of warts on hands, arms and feet	Definition of Drugs Under as per Section 3(b)(i)	2/23/2018
18	29/Misc/03/2018-DC (03)	M/s Magal Health Care Pvt.Ltd., No.34,2nd Floor, 60 Ft.Road, NGEF Layout,,RMV Iind Stage,Sanjaynagar-560094,Bangalore	Rythmic evolution infusion pump without intravenous set/catheter/spike set	Used for administration of prescribed liquid medication and solutions to the body	Not Notified	2/23/2018
19	29/Misc/03/2017-DC (184)	M/s Dialec Medical Services Pvt.Ltd., Plot No.311,Survey No:-197,Block GA, 1st Floor, 1st cross, M.S.Nagar, Opp Ayyapa temple, bengaluru-560038,Karnataka	Citra-Lock solution is claimed to be having anti microbial,anti coagulant and anti bio film properties	Used for prevention catheter related bacteremia and clotting	Regulated	2/26/2018
20	29/Misc/03/2018-DC (68)	M/s NA Life Science, No.19,5th street, Banker's Colony, Kumaran Nagar, Vayalur Road,,Trichy-620017	Fever Cooling Patch	Used for fever management,temporary relief oh headache,toothache and muscle pain	Not Notified	2/27/2018
21	29/Misc/03/2018-DC (78)	M/s CURA Healthcare Pvt.Ltd., No.A-32,Phase-1,MEPZ SEZ, Tambaram Kadapperi,chennai-600045,Tami Nadu,India	Electro mechanical equipmet (Accupush) Hypodermic syringes,hypodermic needles and catheter(extension tube)	Nil	Not Regulated Regulated	3/13/2018
22	29/Misc/03/2018-DC (80)	M/s Freyr Software Services Pvt.Ltd., Level 4,H-08 Building,SEZ Location-Phoenix Infocity Pvt.Ltd., Advance Business Hub, Gachibowli,Telanagan-5600081	Polisorb Devioce (Mineral based gastrointestinal detoxifier)	used for the treatment of diarrhea,nuasea, vomiting,flatus, bellyache,food borne and drug allergic reactions in adults and children	Regulated	3/13/2018
23	29/Misc/03/2018-DC (54)	The Deputy Drugs Controller (I),4th Floor,Zonal FDA Bhawan,GMSD Compund, Bellasis Rd., Mumbai Central,Mumbai-400008	Vaprox HC Sterilant	Used as an antimicrobial (effectice against viruses, bacteria, yeasts and bacterial sporeS) when used in V PRO low temperature sterilization system	Regulated	3/16/2018
24	29/Misc/03/2018-DC (101)	M/s Uber Diagnostics pvt.Ltd., No.1670,1st Floor, 18th cross, MC Layout,Vijayangar,Bangalore-560040	Cardiotrack device (12 Chennel ECG Device)	To conduct Clinical trials /validations	Not Notified	3/15/2018
25	29/Misc/03/2018-DC (25)	M/s Samson Laboratories Pvt.Ltd., SCO 40,Swastik Vihar, MDC, Sector-5,Panchkula-134109	Motion Sickness Patch	Intended to provide relief from vomiting, nausea, anorexia and other symptoms resulted from sickness of cars, ships, airplanes and other means of transport	Regulated	3/19/2018
			Warmer pad/Menstrual Cramp relief patch	Intended for temporary relief of minor menstrual cramp pain and assocaited back aches by way of heat therapy		3/19/2018

			Cooling Gel Patch	Intended for reducing temperature in fever, relief in tiredness ,sleep ,daze,toothache,headache etc.		3/19/2018
26	29/Misc/03/2018-DC (90)	M/s GlaxoSmithKline Consumer Pvt.Ltd., 24-25 Floor, One Horizon Center, Sector-43,dlf Phase -5,Golf Course Road, Gurgaon-122001,Haryana	Nasal Congestion Device	Used for reliving nasal congestion in infants	Not Notified	3/23/2018
27	29/Misc/03/2018-DC (110)	M/s Quantleap Consulting,107,primrose, Serene country,telecom nagar, hyderabad-500032	Diastolic and systolic leg compression device, a non - invasive compression device	Used externally on intact skin (thigh and calf) to enhance blood flow towards proximal parts of the body by increasing tissue pressure in thigh and leg	Not Notified	3/23/2018
28	29/Misc/03/2018-DC (93)	M/s Immito Meditech Pvt.Ltd., 216A, Humayunpur, Safdarjung Enclave, New Delhi-110029	Implantable neurostimulator DBS System	Used to reduce the systoms associated with parkinson`s disease	Not Notified	3/23/2018
29	29/Misc/03/2017-DC (332)	M/s DSS Imagtech Pvt.Ltd., A-5,Mohan Industrial Estate, Mathura Road, Delhi-110002	eXeM Foam Kit containinga syringe with ExEm Gel, A syringe with ExEm water and a coupling device	Intended for recongition of tubal aptency during the ultrasound procedure	Regulated	3/27/2018
30	29/Misc/03/2017-DC (330)	M/s RPK Pharma Pvt.Ltd., Plot No.IV, APHB Colony, Pedagantyada,Vishakhapatnam, Andhra Pradesh-530044	Memthol Barrier Spray	Used to get relief from swelling, pain and irritation in patients suffering from haemorrhoids As per the therapeutic claim, the product attracts the definition of the Drug	Not Notified Regulated	4/3/2018
31	29/Misc/03/2018-DC (107)	m/S Datt Mediproducts Pvt.Ltd., 56,Community Centre, East of Kailash,New Delhi-110065	Velnext foam Dressing Kit	Nil	Regulated	4/3/2018
32	29/Misc/03/2018-DC (65)	M/s BSN Medical Pvt.Ltd., B-10,Lotus Park,Jay Coach Junction, Opp.Raheja Ridgewood, Jogeshwari-400063, Maharashtra	Leukomed IV/IV Film,Fixomull Stretch /Transparent and Leuopor	Intended for holding or fixation of surgical dressings, IV Tubes, catheters etc	Not Notified	4/6/2018
33	29/Misc/03/2018-DC (89)	Monarch Enterprises,6-6-35/2,Kavadiguda, Secudnerabad,Telanagan-500080,Hyderabad	Eurofix, Eurotrasp and Eurosilk	Intended for fixation of dressings, bandagaes, tubes, venous catheters and medical probes etc.	Not Regulated	4/9/2018
34	29/Misc/03/2018-DC (119)	M/s AQS Biocair Pvt.Ltd., Rishi Homes, Flat S1,B-Block, No.191,Samyapuram nagar, 6th Street,Vanagaram,Chennai-600095,Tamil Nadu	Disinfectant solution witha ctive ingredient hypochoilirte ions	Itended to disinfect the home, office, healthcare, ambulances,manfuatcuring unit etc.	Regulated	4/9/2018
35	29/Misc/03/2018-DC (302)	M/s Peroba Ventures Pvt.Ltd., 308,Brigade Gateway Apartements, Dr.Rajkumar Road, Malleswaram,Bengaluru-560055	Sonata Sonograpghy Guided Transcervical Fibroid Ablation system	Intended for providing radiofrequency ablation of uterine fibroids using a transcervical approach without incisions or material uterine distension	Regulated as ÄBLATION DEVICE	4/9/2018

36	29/Misc/03/2018-DC (145)	M/s Predible Health Pvt.Ltd., BN189,Bapuji Nmagar,Pongumoodu,Trivandrum- 695011,Kerala	Predible Liver Software Tool	Intended for 3D Visualization,segmentation and quantative analysis of liver anatomy	Not Notified	4/10/2018
37	29/Misc/03/2018-DC (77)	M/s CURA Healthcare Pvt.Ltd., No.A- 32,Phase-1,MEPZ SEZ, Tambaram Kadapperi,chennai-600045,Tami Nadu,India	SinoPower -S, SinoPower-D and SinoAngio 1200	Used to inject conrtast medium for CT and DSA respectively	Not Regulated	4/12/2018
			Syringe, connecting tube and fill tube	Used to inject contrast medium for CT and DSA respectively	Regulated	
38	29/Misc/03/2018-DC (154)	M/s Medicom International Eyetetch Pvt.Ltd., 305-C, Iris Tech Park, Sohna Road, Sector-48,Gurgaon-122018,India	ICP Ocular Surface Analyzer	Intended to be used for non invasive full assessment of teh ocular surface trthrough a combination of tests for dry eye diagnosis, from tear break up time to teh tear volume production test	Not Notified	4/18/2018
39	29/Misc/03/2018-DC (137)	M/s Mylan Laboratories Limited, Plot No.564/A/22,Road No.92,Jubilee Hills,Hyderabad-500034	EndWartz Freeze	Intende for effective removal of warts from hands, arms and feet by freezing the wart at temperature of -80 degree celcius achieved by pressure mechanism of nitrious oxide (cold gas)	Regulated as ABLATION DEVICE	4/19/2018
			Naloc Pro, an effective solution	Intended for prevention and treatment of nail fungal injection i.e.onychomycosis	Regulated as "Drugs"	
40	29/Misc/03/2018-DC (164)	M/s Intutive Surgical India Pvt.Ltd., C/o Regus Suburb Centres Pvt.Limited, Level 4, Dynasty, A Wing, Andheri- Kurla Road,Mumbai	Instrument Arm Drape,Camera Arm and Head Drape,Column Drape and Arm 4 ExtensioN Drape	Intended to maintains terility of the sterile field when non sterile protions of the da vinci Xi System (IS4000 Surgical System) enter the sterile field by covering the parts of instuments	Not Regulated	4/23/2018
41	29/Misc/03/2018-DC (155)	M/s HP India Sales Pvt.Ltd., Building No.2,DLF Cyber Greens, DLF Cyber City,1-4 Floor,Tower D & E,Phase- III,Gurgaon,Haryana	HP Healthcare Edition HC270cr Clinical review Monitor	Intended to view medical images for image capture verification	Not Notified	4/23/2018
42	29/Misc/03/2018-DC (153)	M/s ConvaTech India vt.Ltd.,SY No.217,Next Logistics Dock -4, Soukya Road, Next to Police Station,Korallur Village, Banaglore-560067	SurePress High Compression Bandage	Intended for use over a primary wound dressing	Not Regulated	4/23/2018
43	29/Misc/03/2018-DC (172)	M/s Divya Baby and Mother care (P) Ltd., 135 F, 2nd Floor, Pocket-IV, Mayure Vihar,Phase-1,Delhi-110091	Divtya Double electric breast pump	Intended to be used to smoothen the flow of milk from breast	Not Notified	4/24/2018
44	29/Misc/03/2018-DC (64)	M/s Alcon Laboratories (India) Pvt.Ltd., 3rd Floor, Crescent-4, Prestige shantiniketan,Whitefield,Bangalore- 560048	CyPass Ultra System	Intended to be used in conjugation with cataract surgery for reduction of intraocular pressure	Regulated	4/26/2018

45	29/Misc/03/2017-DC (296)	M/s Transpact Enterprises Pvt.Ltd., 204, Timmy Arcade, Makwana Road, MaroLA, nheri East, Mumbai- 400059, Maharashtra, India	Vestibulator	Intended for vestibular, neuro developmental and sensory integration therapy	Not Notified	5/1/2018
46	29/Misc/03/2018-DC (111)	M/s Dorthom Medi Dents Pvt.Ltd., UNRA 25A, NCC Road, Ambalamukku, Peokada, Thiruvanantha puram-695005	GRABIO GLASCERA	Used in dental periodontal, oral and maxillofacial surgical procedures to enhance the bone regeneration in lost or fractured bone areas, procedures to enhance the bone regeneration in lost or fractured bone areas	Regulated	5/9/2018
			Foreign Body Retrieval Hood	It is used to retrieve shape foreign objects from GI tract through the scope. It is fixed on the tip of endoscope to protect mucosal tear and to prevent esophagus tare while removing sharp foreign bodies.		
			Balloon Inflation Device	To Inflate Balloon		
			EUS Balloon	For the help of balloon examination of structures within or adjacent to the intestinal wall over the EUS scope		
			Multi Band Ligator	Used for endoscopic ligation of esophageal varices at or above gastro esophageal junction		
			Loop Basket	Used for endoscopic retrieval of foreign bodies from GI tract and to retrieve polyp through colonoscope		
			Polypectomy Snare	Used for endoscopic excision of polyps using single mono polar electrosurgical unit and retrieval of foreign bodies from GI tract		
			Spring Tip Steel Guide Wire	Used to guide esophageal dilators for dilatation		
			Neg Guide Wire	Used to gain access through difficult biliary and pancreatic strictures. To facilitate exchange of compatible wire guided accessories to the desired biliary or pancreatic ducts.		
			Hydra Neg Guide Wire	Used to gain access through difficult biliary and pancreatic strictures. To facilitate exchange of compatible wire guided accessories to the desired biliary or pancreatic ducts.		
			Nitinol Black Wire	To gain access through difficult biliary and pancreatic strictures. To facilitate exchange of compatible wire guided accessories to the desired biliary or pancreatic ducts.		
			Hydra Neg Combo Guide Wire	Hydra neg combo guide wire with tip at both end used to gain access endoscopically through the difficult strictures.		

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29/Misc/03/2018-DC (126)

M/s Shaili Endoscopy ,Plot No.210
&213, Padara Jambusar Road, Dabhasa,
Padra,Vadodara-391440,Gujarat

Stiff Guide Wire	Used to gain access endoscopically through difficult strictures
Super Stiff Hydra Neg Guide Wire	Used to gain access through difficult biliary and pancreatic structures and to facilitate exchange of compatible wire guided accessories to the desired biliary or pancreatic ducts
Wire Guided Stone Extraction Balloon	Used for endoscopic extraction of biliary stones
Single Action Stent Introducer System	Used for easier stent placement and endoscopic biliary stent placement to reduce time
Stent Pusher	For endoscopically biliary stent placement
Biliary Dilator	Used to dilate papilla or biliary strictures through the scope.
ERCP Cannula	Used endoscopically to opacify the biliary duct with radio opaque contrast material for fluoroscopic view
Suction Coagulation Probe	Used for suction and coagulation during endoscopic mucosal resection
Esophageal Dilator	Used to dilate esophageal strictures over previously placed wire guided
Cytology Brush	Used to collect cells from upper and lower gastrointestinal tract
Eso Gastric Balloon Deflation Device	To deflate previously placed ESO gastric balloon
Stone Grasper	Used to facilitate manipulation/ removal of stones can also be used for removing stents from urinary tract
Eso Gastric Balloon Retrieval Device	For retrieval of ESO gastric balloon
Stone Basket	Indicated for the manipulation and removal/retrieval of stones from urinary tract
Nephrostomy Basket	Indicated for the manipulation and removal/retrieval from urinary tract
Probe For Nephrostomy Basket	To apply lithotripsy to break stone from urinary tract
Neg Guide Wire	Used to gain access endoscopically urology through the difficult strictures in urinary tract
Hydra Neg Guide Wire	Used to access urologytract for access and exchange of accessories in urinary tract
Nitinol Black Wire	To gain access through difficult urological strictures. To facilitate exchange of compatible wire guided accessories

Regulated

5/9/2018

			<table border="1"> <tr> <td>Hyneg Combo Guide Wire</td> <td>Used to gain access endoscopically through the difficult strictures.</td> </tr> <tr> <td>Stiff Guide Wire</td> <td>Used to gain access endoscopically through the difficult strictures</td> </tr> <tr> <td>Spray Probe</td> <td>Used to spray dyeing</td> </tr> <tr> <td>Cournual Cannulation Set</td> <td>Used for ovarian cannulation</td> </tr> <tr> <td>Clips For Endoclip</td> <td>Used to mechanically bind blood vessels</td> </tr> <tr> <td>Endoclip Applicator</td> <td>It is a delivery system used to deliver clips for achieving emostatis for:mucosal/submucosal defeats, bleeding ulcers/arteries, surgery sites</td> </tr> <tr> <td>Clipping Device</td> <td>It is used to close two mucosal surfaces without the need for surgery or suturing or used to mechanically bind blood vessels (the device holds the clips)</td> </tr> <tr> <td>Sphincterotome</td> <td>It is used for endoscopic cannulation of biliary ductal system. It is a triple lumen catheter accommodating a guidewire, cutting wire, contrast medical channel</td> </tr> <tr> <td>Needle Knife</td> <td>It is used for precut paillotomy.It has triple lumen design facilitating for cannulation after incision of the pailla without requiring that the catheter be exchanged. Triple lumen accomodates a guidewire, cutting wire and conrast medical injection channel.</td> </tr> </table>	Hyneg Combo Guide Wire	Used to gain access endoscopically through the difficult strictures.	Stiff Guide Wire	Used to gain access endoscopically through the difficult strictures	Spray Probe	Used to spray dyeing	Cournual Cannulation Set	Used for ovarian cannulation	Clips For Endoclip	Used to mechanically bind blood vessels	Endoclip Applicator	It is a delivery system used to deliver clips for achieving emostatis for:mucosal/submucosal defeats, bleeding ulcers/arteries, surgery sites	Clipping Device	It is used to close two mucosal surfaces without the need for surgery or suturing or used to mechanically bind blood vessels (the device holds the clips)	Sphincterotome	It is used for endoscopic cannulation of biliary ductal system. It is a triple lumen catheter accommodating a guidewire, cutting wire, contrast medical channel	Needle Knife	It is used for precut paillotomy.It has triple lumen design facilitating for cannulation after incision of the pailla without requiring that the catheter be exchanged. Triple lumen accomodates a guidewire, cutting wire and conrast medical injection channel.		
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48	29/Misc/03/2017-DC (334)	M/s Glowtronics Pvt.Ltd., 1D, Hootagalli Industrial Area,Mysore-570018,India	<table border="1"> <tr> <td>Double Pin Bipolar electrode</td> <td>Itnded for ENT Surgery usingquantam molecular resonance generator</td> </tr> <tr> <td>Laparoscopic Scissors</td> <td>Designed to cute,dissect,manipultae and /or cauterize various tissues during endoscopic/laprosopic surgical procedures</td> </tr> <tr> <td>Single use Bladder Evacuator</td> <td>Used to intoroduce fluids into body cavities other than blood vaessels,drain fluids from body caivities or avaluate certain physiologic conditions</td> </tr> <tr> <td>Dsisposable lap electrode L Hook and Spatula</td> <td>Used in Laprosopic surgery for cauterizing and manipulation of tissues and veseels</td> </tr> <tr> <td>Laparoscopic Graspers</td> <td>Used to grasp tissue, retrieve foreign bodies, and remove tissues from within the gastrointestinal tract</td> </tr> <tr> <td>Laparoscopic Irrigation Suction Set (LISS Assembly and body probe)</td> <td>Used to introduce fluids into body cavities other than blood vessels, drain fluids from body cavities, or evaluate certain physiologic conditions.</td> </tr> <tr> <td>Single use Biopsy Forceps</td> <td>Used to collect tissue, or foreign body retrieval, from Gastrointestinal tract using an endoscope</td> </tr> <tr> <td>Multiple Band Ligator</td> <td>Used for endoscopic ligation of oesophageal varices and anorectal haemorrhoids</td> </tr> </table>	Double Pin Bipolar electrode	Itnded for ENT Surgery usingquantam molecular resonance generator	Laparoscopic Scissors	Designed to cute,dissect,manipultae and /or cauterize various tissues during endoscopic/laprosopic surgical procedures	Single use Bladder Evacuator	Used to intoroduce fluids into body cavities other than blood vaessels,drain fluids from body caivities or avaluate certain physiologic conditions	Dsisposable lap electrode L Hook and Spatula	Used in Laprosopic surgery for cauterizing and manipulation of tissues and veseels	Laparoscopic Graspers	Used to grasp tissue, retrieve foreign bodies, and remove tissues from within the gastrointestinal tract	Laparoscopic Irrigation Suction Set (LISS Assembly and body probe)	Used to introduce fluids into body cavities other than blood vessels, drain fluids from body cavities, or evaluate certain physiologic conditions.	Single use Biopsy Forceps	Used to collect tissue, or foreign body retrieval, from Gastrointestinal tract using an endoscope	Multiple Band Ligator	Used for endoscopic ligation of oesophageal varices and anorectal haemorrhoids	Not Regulated	5/9/2018		
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			<p>Cholangiography Clamp</p> <p>Used for diagnostic evaluation of bile ducts during laproscopic cholecystectomy. They are designed to grasp and introduce contrast medium into gallbladder for evaluation of stones, blockage and or other abnormalities</p>		
			<p>Endoscopic Ultrasound (EUS) Needle</p> <p>Used to sample targeted submucosal gastrointestinal lesions through the accessory channel of an ultrasound endoscope</p>		
			<p>Pleural drain</p> <p>Used to drain fluids from the chest cavity</p>		
49	29/Misc/03/2018-DC (87)	M/s Confident Sales India Pvt.Ltd., No.47,2nd floor, Pete Channappa Industrial Estate,Magadi Main Road, Kamakshipalya,Bangalore-560079	<p>Clearfill SE Bond</p> <p>Intended use direct filling restorations using light curing composite or compomer, cavity sealing as pretreatment for indirect restorations, treatment for hypersensitive and/or exposed root surfaces, intraoral repair of fractured facing crowns made of porcelain,hybrid cermics or composite resin, surface treatment of prosthetic appliances made of pprcelain,hybrid cermics or composite resin, surface treatment of prosthetic appliances made of porcelain, hybrid ceramics and cured composite resin</p>	Not Regulated	5/11/2018
			<p>Panavia F2.0</p> <p>Intended use cementation of metal crowns and bridges, inlays and onlays, porcelain crowns, veneers,resin crowns, adhesion bridges, endodontic cores and prefabricated post bonding</p>		
			<p>Clearfill AP-X</p> <p>Intended use direct restorations for anterior and posterior teeth Class III,IV,V restorations of anterior teeth,cervical cavities of root surfaces defects</p>		
			<p>Clearfill AP-X Esthetics</p> <p>Intended use direct restorations for anterior and posterior teeth (Class I-V Cavities),Direct veneers,coorection of tooth position and tooth position and tooth shape (diastemna closure, dwarfed tooth), Intraoral repairs of fractured crowns/bridges</p>		
			<p>Clearfill AP-X Flow</p> <p>Intended use -Direct restorations for anterior and posterior teeth (Class I-III Cavities, cervical caries,root erosion), cavity base/liner, intraoral repairs of fractured crowns/bridges/composite resin</p>		

			Alloy Primer	Intended Use adhesion of metal inlays, onlays, crowns ,bridges and metal posts, repair of fractured resin based facing crowns and porcelain fused metal crowns and bridges, fabrication of removable dentures with metal base clasp or attachment, repair of denture		
			Caries Detector	Intended use detects carious dentine for cavity preparation		
			Ceramic Primer	Intended use surface treatment of porcelain, ceramics, hybrid ceramics or composite resin, intra-oral repairs of fractured crowns/bridges made of porcelain, ceramics, hybrid ceramics, hybrid ceramics or composite resin		
			Clearfill SA Luting	Intended Use Cementation of crowns, bridges, inlays and onlays, made of ceramic (such as zirconia and alumina) ,composite resin on metal, cementation of metal cores, resin cores, metal posts or glass fiber posts		
			Clearfill Photo Bond	Intended Use-Enamel and dentin bonding agent for direct composite restorations		
50	29/Misc/03/2018-DC (176)	M/s A V Medical Systems, 18,1st Floor, B1/16,New Kondli, Mayur Vihar, Phase-III,Delhi-110096	Surgical Incision Closure	Intended for surgical closure as Class B device under the provision of D & C Act and MD Rules 2017	Not Notified	5/11/2018
			Drainage Tube Fixing	Intended to fix Drainage catheters and ventilation mask used during endoscopy allowing intraprocedural treatment of respiratory complications without interrupting the procedure		
52	29/Misc/03/2018-DC (192)	M/s Cook India Medical Devices Pvt.Ltd., 4/249-A,Rasim Enclave, Poonamallee High Road,Goparasanallur, Kattupakkam,Chennai-600056,Tamil Nadu	Tissue grafts, staple line reinforcement and dural grafts derived from animal origin	Intended to reinforce soft tissue and as a substitute for repairing dura matter	Regulated	5/11/2018
53	29/Misc/03/2018-DC (128)	M/s Premier Enterprises, No.39/2,South Street, Chatrapatti-626102, Via Rajapalayam,Tamil Nadu	DeRoyal Solidifier	Intended to be used to quickly and completely solidify blood and body fluids for disposal	Not Notified	5/15/2018
			Safeliner semi-rigid liner system	Intended to be used to aid in the management and disposal of waste fluid during variety of medical procedures		
54	29/Misc/03/2018-DC (159)	M/s Nobel Biocare, UnitNo.702,7th floor,A Wing, Supreme Business Park, Supreme City,Powai,Mumbai-400076	AdvanSync 2 (Orthodontic Dental Bracket)	Intended to be used during orthodontic treatment to move the teeth	Not Notified	5/15/2018

55	29/Misc/03/2018-DC (158)	M/s Nobel Biocare, UnitNo.702,7th floor,A Wing, Supreme Business Park, Supreme City,Powai,Mumbai-400076	Orthodontic Dental Bracket	Intended use during orthodontic treatment to moveteeth	Not Notified	5/15/2018
56	29/Misc/03/2018-DC (205)	M/s Medicom International Eyetetch Pvt.Ltd., 305-C, Iris Tech Park, Sohna Road, Sector-48,Gurgaon-122018,India	Evolve Eye Mask (Reusable moist heat mask)	Intended for soothing relief for tired and sore eyes and soothing relief for gritty sensation or irritation on the external closed eye surface	Not Notified	5/15/2018
57	29/Misc/03/2018-DC (204)	M/s ConvaTech India vt.Ltd.,SY No.217,Next Logistics Dock -4, Soukya Road, Next to Police Station,Korallur Village, Banaglore-560067	Unometer Safeti Plus containing tubing and urinary drainage bag without catheter	Intended for collection and measuring the urine voume output in critically ill patients	Not Regulated	5/15/2018
58	29/Misc/03/2018-DC (22)	M/s Digital e-Life Pvt.Ltd., Kamalini Building,Top Floor, Central Avenue Road,Chembur (E),mumbai-400071	Hydropumps, Vibe Rings, Power Rings and related accessories	Intended for non medical use	Not Regulated	5/15/2018
59	29/Misc/03/2018-DC (210)	M/s BSN Medical Pvt.Ltd., B-10,Lotus Park,Jay Coach Junction, Opp.Raheja Ridgewood, Jogeshwari-400063, Maharashtra	LeukoFix and Fixomull Gentle Touch dressing	Inetnded for holding or fixation of dressings,catheters ,IV Tubes,cannulae,etc.	Not Regulated	5/22/2018
60	29/Misc/03/2018-DC (217)	M/s Riddhi Associates, B-276,Okhla Industrial Area,Phase-1,New Delhi-110020	MiniMizer Gastric Ring	Intended to be used in gastric bypass and sleeve gastrectomy operations, for sustained and effective weight loss in bariatric surgery	Not Notified	5/22/2018
61	29/Misc/03/2018-DC (164)	M/s Intuitive Surgical India Pvt.Ltd.,C/o Regus Suburb Centres Pvt.Ltd., Level-4,Dynasty, A-Wing, Andheri-Kurla Road, Mumbai	Instrument Arm Drape,Camera Arm and Head Drape,Column Drape and Arm 4 ExtensioN Drape	Intended to maintains terility of the sterile field when non sterile protions of the da vinci Xi System (IS4000 Surgical System) enter the sterile field by covering the parts of instuments	Not Regulated	5/24/2018
62	29/Misc/03/2018-DC (230)	The Drugs Controller, Govt of Rajshthan,Drug Control Organtization, Swasthya Bhawan,Tilak Marg, Room No.308,3rd Floor, Jaipur,Rajasthan	Mucus extractor,Double J Stent,Abdominal Drain Kit having drainage catheter and collection bag, Polypropylene Non Absorbable synthetic surgical mesh,Bone Wax,Pressure Monitoring Line/High Pressure Extension Line	Nil	Regulated	5/24/2018
63	29/Misc/03/2017-DC (334)	M/s Glowtronics Pvt.Ltd., 1D, Hootagalli Industrial Area,Mysore-570018,India	Laposcopic Grasper Single use Biopsy Forceps	Intended to grasp tissue, retrieve foreign bodies and remove tissues from within the gastrointestinal tract Intended to collect tissue or foreign body retrieval, from Gastrointestinal tract using an endoscopy	Regulated	5/28/2018

			Multiple Band Ligator	Intended for endoscopic ligation of oesophageal varices and anorectal haemorrhoids		
64	29/Misc/03/2018-DC (206)	M/s BSN Medical Pvt.Ltd., B-10,Lotus Park,Jay Coach Junction, Opp.Raheja Ridgewood, Jogeshwari-400063, Maharashtra	Delta Dry Stockinetter	Intended to be used for the protection of skin undercasing materials	Not Regulated	5/30/2018
			Delta Dry Reyonsa	Intended to be used to keep the skin dry		
65	29/Misc/03/2018-DC (181)	M/s Medicom International Eyetetch Pvt.Ltd., 305-C, Iris Tech Park, Sohna Road, Sector-48,Gurgaon-122018,India	E>Eye Medical Equipment	Intended to treat dry eye syndrome	Not Notified	6/6/2018
66	29/Misc/03/2018-DC (246)	M/s GPC Medical Ltd., M Block, DDA, LSC, Vikas Puri, New Dlehi-110018	Oxygen Catheter	It is used for direct administration of oxygen through the naso pharynx.	Regulated	6/13/2018
			Kehr's T Tube	It is used for short term post-operative drainage of common bile duct.		
			Female Catheter	It is used for short term bladder catheterisation through urethra in females.		
			Chest/Thoracic Drainage Catheter	It is used for post operative drainage after cardio thoracic surgery.		
			Thoracic Trocar Catheter	It is used for rapid non operational pleural and chest drainage.		
			Mucus Extractor	It is used for aspiration of secretion from oropharynx in newly born babies.		
			Redon Drainage Catheter	It is an effective device for close wound drainage under negative pressure with the option to use one catheter or two catheter simultaneously.		
			Yankaur Suction set	It is used for removal of secretion and blood pass during surgical procedure		
			Pressure monitoring line	It is used for high pressure monitoring and connection between syringe and infusion pump.		
			Male external catheter	It is used for urine incontinence in male patient		
67	29/Misc/03/2018-DC (252)	M/s Bio India Interventional Technolgoies Pvt.Ltd., Plot No.14,Unit A-2,Near Charak Pharma,Umbergam, Dist.Valsad, Gujarat-396171	Oactive Knee Brace	Inetnded for mild to severe unicompartmental knee osteoarthritis	Not Regulated	6/13/2018
68	29/Misc/03/2018-DC (182)	M/s Tripod Healthcare Pvt.Ltd.,3, Circus Range, Kolkata-700019,West Bengal,India	Smarport Disposable Paproscopic Access System is a sterile device containing a path of entry cannula (with a one way stop cock)	Intended to be used for creating a path of entry through tissue planes and or potential spaces and maintain a working channel for the passagage of laparoscope/endoscope/instrument/device for performing minimal access surgery	Regulated	6/13/2018

70	29/Misc/03/2018-DC (55)	M/s Confident Sales India pVt.Ltd., No.47,2nd floor, Pete Channappa Industrial Estate, magadi Main Road, Kamakshipalya, Bangalore-560079	MD-Chel Cream	EDTA Cream used to clean root canal of pulp, blood vessels, nerve net using a rotary root canal instrument by removing inorganic substance by chelation action. Only used for cleaning purposes, will not remain in the root canal.	Not Regulated	6/14/2018
			MD-Cleanser	Used to cleanse the root canal, is in liquid form and removes the inorganic substance from the root canal. Only used for cleaning purposes, will remain in the root canal		
			Adseal Resin based root canal sealer	Resin based root canal cement. Allows creation of hermetic seal of root canal/		
			Gutta Percha Points	Used to fill the root canal after cleaning and shaping the root canal		
			Absorbent Paper Points	Used to dry the root canal		
			Metapex Calcium Hydroxide with Iodoform	Premixed paste, radio-opaque, provided in Syringe for easy delivery of the paste to the Canal		
			NexPost Fiber Post	Glass Fiber Post, light translucency for efficient light cure deep into the root canal & optimal Flexural Strength (close to dentin)		
			NexCore Dual Cured core build Up material	To restore lost tooth structure, strong cement helps build it		
			MD-Temp Plus Hydraulic Temporary Restorative	Temporary filling material used to close the cavity after tooth cutting		
			NETC Non-Eugenol Temporary Cement	Contains Zinc Oxide, Spontaneous setting. Material used to make a temporary crown until permanent crown can be prepared		
			Meta Etchant	Use for conditioning of dentin surface so that later the filling will adhere to the tooth. Also for conditioning Enamel to fix Inlay/Onlay on the tooth		
			Meta P & Bond	Bonding for porcelain, direct composite, metal Repair, set amalgam and post		
			Biner LC	Used as a cavity liner before making permanent. Filling this has better thermal conductivity. It also stimulates formation of secondary dentin.		
			Nexcomp	Used for composite & porcelain repairs, allows optimum handling, excellent sculptability for restoring natural shape & function		
Nexcomp Flow	Low viscosity, light-cured, radio-opaque flowable composite resin for minimally invasive cavity preparation.					
			Turp (Transurethral Resection of Prostate) Loops	Intended to Reduce the Size of prostate gland entering through urinary tube of male patients by removing abnormal tissues (Class C)		

71	29/Misc/03/2017-DC (331)	M/s Mysore Wilfiltronics Pvt.Ltd., A-4A,Hootagalli Industrial Area, Mysore-570018,Karnataka,India	Diathermy Loops	Intended for excision, conagulation or electro-conization of abnormal tissue, growth or lesions in teh cervix called cervical intraepithelial neoplasia (CIN) and HPV related condylomata acuminata,in combination with ane lectrosurgical generator (Class C)	Regulated	6/14/2018
			Tubr-bi-probe	Intended for surgery in conjunction with surgical septoplasty under anesthesia using endoscopy and incision in lining tissue around tubinate by cauterizing with radio frequency or elctrical current (Class C)		
			Resaflex Probe	Intended for pcedure to dissolve scar tissue around entrapped nerves in the Epidural Space of spine to enable reach of cortisone into affected areas.The procedure involves inserting the function part of the probe into skin and deeper tissues to dissolve the scar tissue using resonance (Class C)		
			Resadisc Probe	Intended for procedure to dissolve scare tissue around entrapped nerves in the Epidural space of spine to enable reach to cortisone into affected areas. The procedure involves inserting the function part of the probe into skin and deeper tissues to dissoolve the scar tissue using resonance (Class C)		
			Lap Loop	Intended for Amputates the uterine orpus from the cervix during laproscopicsupracervical hysterctomy (Class c)		
72	29/Misc/03/2018-DC (268)	M/s Septonent Healthcare India pvt.Ltd., C-1/2,MODC, Taloja, Panvel, Dist.Raigad-410208	septo etch, secure Bond ,Endure Nano and Endure Flow	Used for restoration of tooth	Not Regulated	6/19/2018
73	29/Misc/03/2018-DC (269)	M/s Koye Pharmaceuticals Pvt.Ltd., A-10,Art Guild House,Phoenix Market City Annexe, LBS Marg, Kamani,Kurla,Mumbai-400070	Lubo Airway Collar	Intended for open airway and immobilization of the cervical spine in traumatic patients on emergency situations	Not Regulated	6/19/2018
74	29/Misc/03/2018-DC (277)	Shri Saurin Gandhi, 7/159,Jain Paradise, Jain Society, Sion (Wets),Mumbai-400022	Oximeter, Nebulizer, Bed Wetting alaram and Air Pollution	Nil	Not Regulated	6/22/2018
75	29/Misc/03/2018-DC (186)	m/S Datt Mediproducts Pvt.Ltd., 56,Community Centre, East of Kailash,New Delhi-110065	Bovine Thrombin Powder used for manufacturing haemostatic patch	Intended for topical dressing for emergency use in case of sevreeley bleeding wounds	Does not have predicate device	6/27/2018

76	29/Misc/03/2018-DC (227)	M/s TS Comprozone Pvt.Ltd., Office No.1,Swaralata Apt., Off Gokhal;e Road, Naupada,thane-400602,Maharashtra	Endovenous laser therapy of Varicose Veins	Used for laser pulse	Regulated	6/28/2018
77	29/Misc/03/2018-DC (294)	M/s Agastya Software Pvt.Ltd., Office NO.121,Corethum ,Plot NO.A-41,Sector-62,Noida-201301	Pcket ECG Device -Sanker Life	Intended to Monitor ECG	Not Regulated	6/28/2018
78	29/Misc/03/2018-DC (255)	M/s Carl Zeiss India (Bnagalore) Pvt.Ltd., Plot NO.3, Block 2,Vision Jigani Link Road, Bommasandra Industrial Area,banaglore-560099	External Eyelid weight Eyelid weight implants Ptose- up Ptosis Probe Symblepharon Ring Metaireau Tubes	Intended for lagophthalmos for temporary facial paralysis or bell's palsy Designed for the gravity-assisted treatment of the functional defects of lagophthalmos resulting from facial paralysis. The implantation of a weight implant allows a passive reanimation of the eyelid to correct functional defects such as ocular irritation, Conjunctival dessication, Conjunctivitis, Keratitis, Corneal ulceration, Epiphora and Pain and discomfort. Surgical treatment of ptosis requiring brow suspension, where levator palpebrae are unusable. The band is placed between the tarsal plate and occipitofrontalis muscle. Surgical treatment of ptosis requiring brow suspension and Ptosis probe is autogenous or homologous materials offer the following advantages such as reduced operating and hospitalization time as well as a single operative site. Elimination of the inherent morbidity linked to harvesting autogenous material. Implantable device as circular band used to prevent the eyelid from adhering to the eyeball and occasionally for glaucoma.Prevent the retraction of the conjunctival culs-de-sacs.The Wide central hole avoids corneal contact while preserving the cornea It is used for lacorhinostomy derivation between the internal canthus and the nasal fossa Dacryocystorhinostomy (conventional or laser).	Regulated	7/3/2018
79	29/Misc/03/2018-DC (281)	M/s Geetha Manunath,PhD, Co foudner CEO,Niramal Health Analytix Pvt.Ltd., A7-506,Elita Promenade, J P Nagar, 7th Phase,Banagalore-78	Thermalytix,a non -invasive device	Intended to be used for Diagnostics of breast cancer	Not Notified	7/5/2018

80	29/Misc/03/2018-DC (297)	M/s. Regency Lifesciences India Pvt. Ltd., 8, 4th A Cross, 5th Main, HRBR 2nd Block, Kalyanagar, Bangalore-560043	Duragraft Vascular Conduit Storage	Nil	Nil	7/5/2018
81	29/Misc/03/2018-DC (12)	M/s Reckitt Benckiser (India)pvt.ltd., Plot No.48,Sector-32,Institutional area, gurgaon-122001	Durex Play Lubricant	Intended to ease vaginal dryness and intimate discomfort and applied to intimate areas prior to sexual intercourse	Under the definition of Drug/New Drug	7/5/2018
82	29/Misc/03/2018-DC (241)	M/s. Cloudncare E-Health Pvt.Ltd., A-402 Ridgeview, IFS Society, Sector 54,Gurgaon-122011, Haryana	Virtual Reality anatomy 3D Visualization table	Intended for medical imaging, digital learning, peroperative image analysis and simulation	Not Notified	7/18/2018
83	29/Misc/03/2018-DC (347)	M/s CliniExperts Sservices Pvt.Ltd., Unit No.325,City Centre mall, Plot No.5,Sector-12,Dwarka,New Delhi-110075	Negative pressure wound therapy device	Used to enhance and promote wound healing in acute, chronic and burn wounds	Regulated	7/20/2018
84	29/Misc/03/2018-DC (225)	M/s Carl Zeiss India (Bnagalore) Pvt.Ltd., Plot NO.3, Block 2,Vision Jigani Link Road, Bommasandra Industrial Area,banaglore-560099	Lacrimal Dialator and probes	Used for exploring the lacrimal canal (the lacrimal duct) during an ophthalmic procedure	Not Regulated	7/23/2018
			Punctum Dilator and Plug Inserter	Facilities the insert plug portion of all monocular intubation systems into punctum		
			Disposable Iris Retractor	Used for the temporary mechanical dilatation of the margins of the iris during ophthalmic surgery		
			Sizer for autostable intubation set II	Enables to choose the appropriate length of masterka or autostable bicanaliculus intubation set II		
			Sizers Set	Determine the proper orbital implant diameter for enucleation or evisceration		
85	29/Misc/03/2018-DC (170)	M/s NovoMed Incorporation Pvt.Ltd., Shop No.103,the Summit Business BayPrakashwadi,Near Cinemax Cinema, Village Gundavalli,Andhri-Kurla Road, Mumbai-400093	NATROX Oxygen wound therapy system	Intended for wound hearing	Regulated	7/23/2018
86	29/Misc/03/2018-DC (326)	M/s Leixir Resources Pvt.Ltd., 101,Vatika Business Park,Tower-2, Sohna Road,Sector-49,Gurgaon-122018,Haryana	Artificial Teeth (HS Code 90212100) (Customized dental crowns and bridges)	Nil	Not Notified	7/23/2018
87	29/Misc/03/2018-DC (329)	M/s Convatec India Pvt.Ltd., SY No.217,Next Logsitics Dock -4,Soukya Road, Next to police station,korallur village, banaglore-560067	Sensi Care Sting Free Adhesive Releaser Spray	Intended to be used for atraumatic removal of medical adhesivces,wound dressings and appliances	Not Notified	7/23/2018
88	29/Misc/03/2018-DC (316)	M/s Skylabz, Plot No.3/156/4D,SKS Nagar, Ayya Ramasubbu Lane Pandikovli ring road, madurai.	Inflation device	Intended to be used for inflating the balloon or stent during angioplasty by creating positive pressure connected to stent delivery catheter	Regulated	7/23/2018

		Law, 1, Mahaveer Ring Road, Industrial-625020, TN	Torque Device	Intended for holding and twisting guidewire during interventional procedures	Not Notified	
89	29/Misc/03/2018-DC (325)	M/s Haitech Medical Solutions Pvt.Ltd., 510, Bhaveshwar Arcade, Annex Area, Opp Shreyas Cinema, Behind Sarawat Coooperative bank, lbs road, Mumbai	Orthomta	Intended for root canal grafting for repair of root perforations, internal resorption and apexification	Not Regulated	7/24/2018
			RetroMTA	Intended for vital pulp therapy for deciduous and young teeth and repair material for permanent teeth		
90	29/Misc/03/2018-DC (333)	M/s Convatec India Pvt.Ltd., SY No.217, Next Logistics Dock -4, Soukya Road, Next to police station, korallur village, banaglore-560067	Sensi Care Sting Free Skun barrier Spray	Intended for the protection of damaged at risk and peri wound skin from the detrimental effects of body waste, enzymes and adhesives	Not Notified	7/24/2018
91	29/Misc/03/2018-DC (343)	M/s FCL Vision (OPC) Pvt.Ltd., D3-Block ,B-1, KH No.69, 1st floor, Mahavir Enclave, New Delhi-110045	Color Perfection (Theatrical eye accessories) reusable conatct	Intended to enhance or alter the apparent colour of the eye	Not Notified	7/24/2018
92	29/Misc/03/2018-DC (357)	M/s BEMPU Helath Pvt.Ltd., #32, Alsa Glenridge Apartment 3C, 3rd floor, Langford Road, Bangalore-560027	BEMPU Apne Boot	Intended to be used to detect and correct apnea for pre maturity	Not Notified	7/24/2018
93	29/Misc/03/2018-DC (274)	M/s CliniExperts Sservices Pvt.Ltd., Unit No.325, City Centre mall, Plot No.5, Sector-12, Dwarka, New Delhi-110075	Import Organ Care system	Nil	Under Regulation	7/25/2018
94	29/Misc/03/2018-DC (355)	M/s Hollister Medical India Pvt.Ltd., Plot No.27, Sector-5, Phase-II, HSIIDC, Growth Center, Bwai-123501, Haryana, India	Stoma Cone Irrigation System	Intended to be used for routine irrigation to regulate emptying of the bowel	Regulated	7/25/2018
95	29/Misc/03/2018-DC (218)	M/s Browndove Healthcare Pvt.Ltd., Plot No.318/A, Harohalli ,2nd pahse, Industrial area, kanakapura Taluq., Kamanagar-562112	Dialyzer with Blood tubing set	Intended for filtering the blood	Regulated	7/26/2018
			Yankauer suction Set	Intended for suctioning of secretions, blood and debris peri-operatively		
96	29/Misc/03/2018-DC (359)	M/s Monitra Healthcare Pvt.Ltd., 202, Mani Niketan, Plot No.496, Defence Colony, Sainikpuri, Hyderabad-500094	ECG Monitor (upBeat), a non-invasive adhesive sensor patch	Intended to be used for detection of heart rhythm disorders	Not Notified	7/27/2018
97	29/Misc/03/2018-DC (358)	M/s Orbit Lifesciences , Mehtra Mahal, 7th floor, 15, mathew road, opera house, mumbai-400004	NeoDiamond Burs	Intended to be used to cut and drill the teeth for root canal treatment	Not Notified	7/27/2018
98	29/Misc/03/2018-DC (342)	M/s Romsons Medicons , E-20, Foundary Nagar, Agra-282006	High Concentration Oxygen Mask, Oxygen Mas and Nebulizer	Intended for delivering oxygen and medication to treat respiratory disorders	Not Regulated	7/31/2018
		M/s Romsons Medicons , E-20 Foundary	Nasal Oxygen	Intended for delivering oxygen for inhaling small amount of supplement		

99	29/Misc/03/2018-DC (328)	M/S ROBINSONS MEDICONS ,E-20,1 Ganga Nagar,Agra-282006	Umbilical cord clamp	Intended to clamp over the newborn infants umbilical cord after delivery and prevent the blood loss	Regulated	7/31/2018
100	29/Misc/03/2018-DC (352)	M/s Evelabs Technologies Pvt.Ltd.,V V Nivas, Archal Nedyara ,P.O.,Anchal Kollam,Kerala-691306	Dripo Smart Infusion Monitor	Intended to be used as supplementary eكتروnic drip monitor in standard gravity infusion and set gravity infusion rates (Flor Regulation)	Regulated	7/31/2018