

2017 Database

S. NO.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	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	02-01-2017
2	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	02-01-2017
3	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	02-01-2017
4	M/s Datt Mediproducts Pvt.ltd., 56,Community Centre, East of Kailash,New Delhi-110065	Velvez	Space occpying dressing, prevents cavity of surgery or trauma patients	Regulated	02-01-2017
		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	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	02-01-2017
6	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 microvasculature in diffuse systemic scleroderma patients	Not Regulated	02-01-2017
7	M/s Think I, C-101, 1st Floor, Sector-2, Noida-201301, UP.	Algorithm (software)	Bosch Mobile Non - mydriatic fundus camera to diagnose diabetic retinopathy using undus images	Not Regulated	02-01-2017
8	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	02-01-2017
9	M/s Cybernoid Healthcare Pvt.Ltd., Plot No.70, 1st Layout, Teachers Colony, Kolathur, Chennai-600099	Cybo Limb	Rehabilitating spinal cord injury patients with lower limb neurological motor deficit	Not Regulated	02-01-2017
10	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	10-01-2017

11	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	10-01- 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	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	10-01- 2017
		Bag Spike			
		Smartsite needle free valve			
13	M/s Genetix Biotech Asia Pvt.ltd., 71/1,1st floor, Shivaji Marg, Najafgarg 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	24-01- 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	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	14-02-2017
15	M/s Hansraj Nayyar Medical India, L8 Laxmi Industrial Estate, Link Road, Oshiwara,Andheri (W),Mumbai-400053	Vented Intubating introducer	airway management	Regulated	14-02-2017
16	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	Regulated	14-02-2017
17	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	14-02-2017
18	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	28-02-2017

19	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	28-02-2017
20	M/s Morulaa Healthtech Pvt.ltd., Plot No.38,1st Floor, Rajeshwari Street, Santhosh Nagar,Khandanchavdi,Chennai-96	Ten20 Conductive Paste	Used as an adhesive to hold non -disposable electoneurodiagnostic electrodes in place on intact skin sites	Not Notified	28-02-2017
		Nuprep Gel	To reduce the impedance of the skin to local potential differentials as measured by electroneurodiagnostic and electrocardodiagnostic equipment		
21	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	28-02-2017
		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	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	15-03-2017
23	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	15-03-2017
24	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 temporary relief of joint pain associated with arthritis:muscle spasms, minor strains and sprains, muscular relaxation and the temporary increase of local circulation where applied	Not Notified	15-03-2017
25	M/s HLL lifecare Limited, HLL Bhavan, Poojappura,P.O.Thiruvananthapuram-695012	Skin Stapler	Nil	Regulated	22-03-2017
26	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 sorbent cartridge 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	22-03-2017

27	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	22-03- 2017
28	M/s Emergo India Consulting Pvt.Ltd.,8/1,1st floor, Vasavi Colony, Kakguda, Near Pciket, Secunderabad,Hyderbad-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	30-03- 2017
29	M/s Truskin Gloves Pvt.ltd., Plot No.14-C,Cochin SEZ, Kakkanad,Cochin-682037,kerala,India	Sterile Surgical Gloves	Nil	Not Regulated	05-04- 2017
30	M/s MTEX (I) Pvt.ltd.,A-26/4,Mohan Co-Operative Industrial Estate,Mathura Road, New Delhi-110044	Rehabliliation brace with BOA Technology	Used in Joint disorders, pre-post-surgical treatment	Not Notified	05-04- 2017
		Nebulizer	used in the treatment of lower sirways respiratory diseases like asthma		
31	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	05-04- 2017

32	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	05-04-2017
33	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	05-04-2017
		Cillika Microscope	Used to help laboratory medicine professional to make a diagnosis through a portable digital platform		
34	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	05-04-2017
		Combined Antineoplastic Thermotheapy bladder recirculation system (Combat BRS V4 System)	Treatment for the treatment of cancerous cells by using thermal energy		
35	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	05-04-2017

36	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	11-04- 2017
37	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	11-04- 2017
38	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	18-04- 2017
		Sponge made with devitalized human amniotic and chorion membrane and gelatin	Used to heal drop ulcers in conjunction with negative wound pressure therapy		
39	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	24-04- 2017
		Hydrosun 750 or 575 an infrared heat treatment device	Used in treatment of degenerative rhematic illness, chronic neuritis, spine disorders		
40	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	24-04- 2017

41	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	23-05-2017
42	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	23-05-2017
43	M/s Siddhi Vinayak Enterprises, 11/343,Geeta Colony,Delhi-110031	New Wings Pain relief patch	To get relief from low back pain,bruises, sprains, stiff neck, joint pain,muscle pain,frostbite	Regulated	23-05-2017
44	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 apnea (OSA) in adults	Not Notified	23-05-2017
45	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	23-05-2017
46	M/s Alaric Aroojis, 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	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	23-05-2017

48	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	30-05-2017
		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 imflammation of the arch of foot		
		Socks to prevent falling	To prevent falling and twisting of ankles		
49	M/s Nano Therapeutics Pvt.Ltd., D-54/2,Hojiwala Industrial Estate,Sachin Surat,Gujarat-394230	Quantacore HD Endobronchial Ultrasound Transbronhial Aspiration Needle (EBUS-TBNA)	Endobronchial ultrasound endoscopes for ultrasound guided fine needle aspiriation of the submucosal masses,lymph nodes and intraperitoneal masses of the tracheobronchial tree and gastrointestinal tract	Regulated	13-06-2017
50	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	13-06-2017

51	M/s Sunheri Marketing Pvt.Ltd., Shri Ram Marg,Huda Bypass,Sector-12,Opposite Indo Spinning Mills,Panipat-132103,Haryana,India	Contactless Infrared Therometer	To measure the temperature of various surfaces, liquids and body	Not Notified	11-07-2017
		Piston Type Nebulizer	To make smooth breath and to transform 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	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	11-07-2017
53	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	11-07-2017
54	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	11-07-2017

55	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 scss for connectors with secondary flashback by releasing the air only	Regulated	18-07- 2017
56	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	18-07- 2017
57	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	25-07- 2017
58	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 Lapsissors 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 elfred,LiNA Clear Sight and LiNA Clear sight Wipe) 8.LiNA Endobag TM 9.LiNA EasyBag TM 10.LiNA Fascia Scalpel 11.LiNA Xcise TM	Sterile and single use devices used for making the port entry in abdominal cavity Surgical equipments	Regulated Not regulated	25-07- 2017

59	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	01-08-2017
60	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	01-08-2017
61	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	07-08-2017
62	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	17-08-2017
63	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	17-08-2017
64	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	17-08-2017
		Zilico (electrical impedance spectrograph devices)	Detecting cervical cancer		

65	M/s Oxygan Solutions Pvt.Ltd., 42 A/B, Yogi Nagar Township, B/S Zenith Tins, N.H.-8,Chennai-391740,Vadodara	95% pure oxygen with and without flavor	All natural and perfect alternative to the energy drinks, shots and supplements	Notified	29-08-2017
66	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	12-09-2017
67	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	12-09-2017
68	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	19-09-2017
69	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-Ketogulterate (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, transporattion and eventual transplantation in to recipient	Not Notified	26-09-2017

70	M/s Mavinbo Services, A/4, Anjali Society, M.Dmarg, Panchakhandi, Thane (West), Mumbai-400602	Histofreezer portable cryosurgical system	Cryosurgical treatment for removal of different types of warts and skin tags	Regulated	26-09-2017
71	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 preparation for storage, transportation and eventual transplantation in to recipient	Not Notified	26-09-2017
72	M/s Emergo India Consulting Pvt.Ltd., 8/1, 1st floor, Vasavi Colony, Kakguda, Near Picket, Secunderabad, Hyderabad-Cir-2, Telangana-500015	TransAeris System	Used in prevention and treatment of ventilator-induced diaphragm dysfunction (VIDD)	Not Notified	04-10-2017
73	M/s Myovatec Surgical System Pvt.Ltd., A-12/42A, MIG DDA Flats, Kalkaji Extension, New Delhi-110019	Conevita's silicon Intra-gastric balloon with radio opaque catheter	Used to induce precocious satiety sensation in obese patients	Regulated	04-10-2017
74	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	04-10-2017

75	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	M/s Goldwin Medicare Ltd., 101/102,Vailankanni Towers, A Wing, Mari Nagar, Off.Senapati Bapat Marg,Mahim (W),Mumbai-400016	Srugical Dressings		Regulated	16-10-2017

2016 Database

S. NO.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	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>	07-01-2016
2	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>	07-01-2016
3	Dr. S. Manivaannon, DDC(I), 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>	07-01-2016
4	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 Stiulator)	Battery operated Electronic device intended for use as an adjunctive therapy for pain management	<u>Not Regulated</u>	19-01-2016
5	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>	19-01-2016
6	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	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	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	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	M/s Lensai opthalmic 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	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	M/s paul hartmann medical Pvt ltd., B/506, 5th Floor titanium Square, Thaltej Ahemedabad-380059, Gujarat, India	Cosmopore I.V Hydrofilm I.V and Hydrofilm I.V Control	control are surgical dressing materials	<u>regulated</u>	16-02-2016
13	Dr. Sharmila Jalgaonkar, member secretary, IEC-I, 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/Pincolabs(Point of care testing(POCT))	analyzing blood samples	<u>Not regulated</u>	16-02-2016
14	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	<u>not covered under the provisions of D7C act</u>	16-02-2016

15	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	<u>product is not yet approved</u>	16-02-2016
16	M/s Sutures India Pvt Ltd., 472 D, 13th Cross, 4th Phase, Peenya industrial Area, bangalore-560058	Prosorb Mesh(Composite of polypropylene and polyglycolic acid)	form 29 for purpose of examination testing and analysis in india	<u>NOC to grant test license in form 29</u>	16-02-2016
17	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	<u>Not regulated</u>	16-02-2016
18	M/s cytocare technologies Pvt Ltd., Hyderabad	Cryomacs Freezing bags transfer sets and clinimacs reagents	for storage of periphral blood Stem cells and cord blood stem cells,	<u>regulated</u>	16-02-2016
19	M/s Sutures India Pvt Ltd., 472 D, 13th Cross, 4th Phase, Peenya industrial Area, bangalore-560058	Trustat(xxidized Regenerated Celloulose)	surgical dressings	<u>Regulated</u>	23-02-2016
20	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	<u>permission to manufacture & sale of the product</u>	23-02-2016
21	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	<u>regulated</u>	23-02-2016
22	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	<u>Not regulated</u>	23-02-2016

23	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.	<u>regulated</u>	23-02-2016
24	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	<u>Not regulated</u>	18-02-2016
25	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	<u>regulated</u>	01-03-2016
26	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	<u>Not regulated</u>	03-01-2016
27	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	<u>regulated</u>	03-01-2016
28	M/s Merck Limited, Shiv sagar Estate, A dr. A.b Road, worli Mumbai-400018	Vented Medical Milex 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	<u>Not regulated</u>	03-11-2016
29	M/s. Agkem Impex pvt Ltd., 503-504, Rishabh corporate tower, Plot No.16, community centre karkadooma, Delhi-110092	Zlrconia Blank, Vintage Art/Hole/MP/ZR/Al, ceramage	ceramage indicat ef ofr vennering of metal framework and copings for the preparation crowns and bridges	<u>Not regulated</u>	22-03-2016

30	Chief Medical Officer, Office of CMO, Sawai Maan Singh Hospital Jaipur, Rajasthan-302004	Heart valves	nil	<u>regulated</u>	22-03-2016
31	M/s Greiner Bio-One(India) Pvt Ltd., The Corenthum, 2111, Tower-A, Plot no.A/41, Sector-62, Noida-201301	Lancet	nil	<u>Not regulated</u>	22-03-2016
32	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 textile treated with chemical i.e (Dimethyltetradecyl 193-trimethoxysilyl) propyl ammonium chloride, a quaternary ammonium salt (QAS) to be used in hospitals, patient care hotels and residence	<u>Not regulated</u>	22-03-2016
33	M/s Surgiplus, Plot No.2, 5th Cross, Ganaprakasam Nagar, Puducherry-605008	Connecting tube with & without Yankauer	nil	<u>regulated</u>	22-03-2016
34	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 trocar-suturer and catheter	<u>regulated</u>	22-03-2016
35	M/s Ace Cardiopathy Solutions Pvt Ltd., 704, 7th Floor, Krishna Apr Business Square, Neata Ji Subhash Place, Delhi-110034	Comfort-In (needle-free & easy-Quick Injection system)	contains syringes and adapter used to deliver 0.5ml volumes of various medications (especially insulin) and vaccines subcutaneously	<u>regulated</u>	04-11-2016
36	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 shape balloon	indicated for patients undergoing laparoscopic surgery requiring tissue separation of the extraperitoneal space	<u>regulated</u>	04-05-2016

37	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	<u>regulated</u>	04-05-2016
38	M/s B I 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	<u>Not regulated</u>	04-05-2016
39	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	<u>regulated</u>	04-05-2016
40	Dr. Shahid Ali Siddiqui, MBBS MD, prof & head, Department of radio-therapy 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)	treatment i	<u>Not regulated</u>	04-05-2016
41	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	<u>Not regulated</u>	04-05-2016
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 intro-nasal surgical	<u>regulated</u>	04-12-2016
43	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	<u>Not regulated</u>	04-12-2016

44	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	<u>Not regulated</u>	04-12-2016
45	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	<u>regulated</u>	04-12-2016
46	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	<u>regulated</u>	19-04-2016
47	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(Hydrid Composit kit, Nano-hybrid composite kit, flowable Kit, Enamel bond adhesive)	used as filler/Restorative material for dental cavities	<u>Not regulated</u>	21-04-2016
48	M/s S. Three Sales International pvt Ltd., M10, Old DLF Market, Sector 14, Gugaon	Clave needle free connector	intended for use as an accessory to intravascular adminstration set for the aminstration of fluids to patient through a cannula placed in the vein or artery	<u>regulated</u>	25-04-2016
49	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	<u>regulated</u>	26-04-2016
50	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	<u>regulated</u>	26-04-2016

51	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	<u>Not regulated</u>	28-04-2016
52	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 sectons of bowel and other tissues structures	<u>Not regulated</u>	05-04-2016
53	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	<u>Not regulated</u>	05-04-2016
54	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 pressur in human beings	<u>regulated</u>	05-04-2016
55	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 lamelar keratoplasty(DALK)	nil	<u>Not regulated</u>	05-04-2016
56	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 tratment(AML1,2,3,4,5,6,7,8)	used for cosmetic purpose	<u>not regulated</u>	08-04-2016

57	M/s Kay & company, 25, netaji Subhaseh marg, new delhi-110002	medical equipments surgical instrument and hospital rubber goods	nil	<u>Not regulated</u>	05-04-2016
58	M/s Chrysalis Healthcare Private Limited, A-5, Golf View Apartment saket, New Delhi	MiniMizer gastric Ring	Insicateg for sustain 7 effective weight loss in bariatirc surgery	<u>Not regulated</u>	05-10-2016
59	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)	<u>Not regulated</u>	05-10-2016
60	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	<u>regulated</u>	05-10-2016
61	M/s Duraent Biologicals Ltds., 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 panceras	<u>not regulated</u>	05-10-2016
62	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	<u>Not regulated</u>	05-10-2016
63	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	<u>Not regulated</u>	05-10-2016
64	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	<u>Not regulated</u>	17-05-2016

65	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 Biright)	used for the manufacturing of non-cardiac stents	<u>Not regulated</u>	17-05-2016
66	M/s Emergo(India) Conulting 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 medica deivce is endometrial biopsy and mechanical removal of the dumulus cell payers of the oocyte	<u>Not regulated</u>	17-05-2016
67	M/s Pro Medic devices., A-13 East Krishna Nagar Swami Dyanand marg, delhi-110015	pacemaker	nil	<u>Not regulated</u>	17-05-2016
68	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 procederes	<u>Not regulated</u>	06-06-2016
69	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	<u>regulated</u>	06-06-2016

70	M/s Bornlife prosthetic & orthotic ins, H-2 Near gurudwara, Lajpat nagar-I, New Dlehi-110024	Rehabilitation goods(prosthetic hip , knee joint, foot, artifical 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).	<u>Not regulated</u>	06-09-2016
71	the drugs controller & Licensing Authroity, 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	<u>regulated</u>	06-10-2016
72	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	<u>Not regulated</u>	13-06-2016
73	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	<u>not regulated</u>	13-06-2016
74	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	<u>Not regulated</u>	14-06-2016
75	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	<u>Not regulated</u>	14-06-2016

76	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	<u>Not regulated</u>	14-06-2016
77	M/s Pure tech health,pant hospital, bhua rani, Kashipur Road, Rudrapur, Uttarakhand-248197	Movas-Electric potential therapy equipment	nil	<u>Not regulated</u>	14-06-2016
78	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)	<u>Not regulated</u>	14-06-2016
79	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	<u>Not regulated</u>	14-06-2016
80	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	<u>Not regulated</u>	14-06-2016
81	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	<u>regulated</u>	14-06-2016
82	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	<u>Not regulated</u>	14-06-2016
83	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	<u>not regulated</u>	14-06-2016
84	M/s Indo-US Supersoeciality 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	<u>Not regulated</u>	15-06-2016

85	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 acrylc teeth	used in prosthetic dentures	<u>Not regulated</u>	15-06-2016
86	M/s Toshbro Medical Pvt Ltd., 1001-1002, vikram tower 16 Rajendra Place, new Delhi-110008	Aneurysm clips, Drill Burrs/cutters, perforators & craniotomes	nil	<u>Not regulated</u>	21-06-2016
87	M/s goldwin Medicare Ltd., 2, Doctor house, 2nd Floor, 124 Perin Nariman Street, fort Mumbai-400001	Synthetic casting tape	nil	<u>regulated</u>	21-06-2016
88	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 finshed medical devices	<u>Not regulated</u>	24-06-2016
89	M/s Alfa corpuscles Private Limited 25/36, East patel Nagar New Dlehi-110008	Enject safety syringe	Clinical trial in respect of prodct i.e. enject safety syrine	<u>regulated</u>	06-09-2016
90	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	<u>Not regulated</u>	22-06-2016

91	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+ KCI+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	<u>regulated</u>	30-06-2016
92	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	<u>Not regulated</u>	07-01-2016
93	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	<u>regulated</u>	07-11-2016
94	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	<u>a), b) c) - regulated</u> <u>d), e) Not regulated</u>	07-12-2016
95	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	<u>regulated</u>	15-07-2016
96	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	<u>regulated</u>	19-07-2016

97	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	<u>regulated</u>	19-07-2016
98	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	<u>regulated</u>	19-07-2016
99	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)	<u>regulated</u>	19-07-2016
100	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	<u>not regulated</u>	19-07-2016
101	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	<u>Not regulated</u>	22-07-2016
102	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	<u>Not regulated</u>	22-07-2016

103	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	<u>Not regulated</u>	22-07-2016
104	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	<u>Not regulated</u>	22-07-2016
105	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	<u>Not regulated</u>	22-07-2016
106	M/s BD India Pvt ltd., 204, Tolstoy house, 15, tolstoy marg, new delhi-110001	PleurX Catheter System- drainage kit , pleurX procedure pack & plexurX lockable drainage line kit consisting of self-adhesive dressing and Alcohol pads	nil	<u>regulated</u>	22-07-2016
107	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	<u>regulated</u>	26-07-2016
108	M/s Aramex Trading co., 9-Ashok Nagar, Lucknow	Dental material Ahfil	used as dental restorative material	<u>Not regulated</u>	08-02-2016
109	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	<u>Not regulated</u>	08-04-2016

110	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	<u>Not regulated</u>	08-08-2016
111	M/s covidien Healthcare India Pvt Ltd., 4th Floor, Tower A & B, SAS tower, medanta the medicity complex, Sector-38, Gurgaon-1220011	trocar	nil	<u>regulated</u>	08-08-2016
112	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	<u>approval</u>	08-09-2016
113	M/s Event medi Systems, 218, vishal tower, District centre, Janakpuri, New Delhi-110058	Balloon inflation device(indeflator) and Haemsotiatic valve kit(Y connector Kit)	nil	<u>Regulated</u>	08-09-2016
114	M/s Scitra International No.5, Sillco valley, Sector-127 S.A.S Nagar, Punjab-140301	Soft cast Bandage	used under POP bandage to give cushioning effect to the patient	<u>Not regulated</u>	08-11-2016
115	M/s Zuventus healthcare ltd., T-184, MIDC, Bhosari, Pune-411026	SiGyn vaginal gel	used for vaginal symptoms in Genitourinary Syndrome during menopause(GSM)	<u>regulated</u>	18-08-2016
116	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	<u>Not regulated</u>	18-08-2016

117	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	<u>regulated</u>	23-08-2016
118	M/s prymax healthcare LLP, Plot no. 53/17, industrial area NIT Faridabad haryana(India)-121001	Disposable perfusion set	Heart lung pack and angio kit including accessories viz, arterial & venous pump lines, arterial filter bypass loops, Y connectors, perfusion tubing manifold etc	<u>regulated</u>	08-09-2016
119	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	<u>NOC for the product</u>	09-05-2016
120	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	<u>regulated</u>	09-06-2016
121	M/s. Access Devices, 28, 12th cross , Indiranagar, 1st stage, Bangalore 560038	Scalp cooling system	used for prevention of chemotherapy induced alopecia	<u>not regulated</u>	09-12-2016
122	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 adjuvntively in surgical procedures to assist in the control of capillary, venous and small arterial hemorrhage when ligation or other conventional methods of cotrol 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	<u>regulated</u>	09-12-2016

123	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 Reprocessing	(A) Used for cleaning hemodialysis , thermochemical disinfection, (B) used for cleaning hemodialsis, cold disinfection (C) used for reprocessing dialyzers machine	<u>regulated</u>	09-12-2016
124	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 of Iodoform	(A) Used for fixation of crown and bridges (B) used for treatment of dry sockets, post extraction dressing	<u>(A) not regulated</u> <u>(B) regulated</u>	09-12-2016
125	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)	<u>regulated</u>	09-12-2016
126	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	<u>Not regulated</u>	09-12-2016

127	The Assistant Drugs Controller (I), room No. 10, International Air-Cargo-Complex, Sahar, andheri, Mumbai-400099	Radiopharmaceuticals / Radio-Immuno assays kits		<u>regulated</u>	09-12-2016
128	M/s. Gale Overseas Trading Pvt. Ltd., Gale House, 5NH/87, NIT, Faridabad-121001	Quease EASE	is indicated for the treatment of chemotherapy induced nausea and vomiting and administered through inhalation	<u>regulated</u>	15-9-2016
129	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	<u>Not regulated</u>	15-09-2016
130	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	<u>regulated</u>	19-09-2016
131	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	<u>regulated</u>	26-09-2016
132	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	<u>regulated</u>	26-09-2016
133	all port offices of cdsco	Trocars	Trocars are regulated under the "Catheters"	<u>regulated</u>	26-09-2016
134	Alleen Clinical Research Services, Dr. Sudhakar Bangera, G-5 Mount Meru Road No. 5, Banjura Hills, Hyderabad-500034	CoAg Stop Bleeding Topical Hemostat powder and foam	intended for use as topical dressings for the management of bleeding wounds	<u>regulated</u>	26-09-2016
135	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	<u>regulated</u>	27-09-2016

136	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)	<u>regulated</u>	13-10-2016	
137	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	<u>Not regulated</u>	13-10-2016	
138	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	<u>regulated</u>	13-10-2016	

139	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 endoscope intended for deep ileoscopy / upper enteroscopy and colonoscopy	(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	<u>(A) not regulated</u> <u>(B) regulated</u>	14-10-2016	
140	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		<u>not covered under the provisions of D7C act</u>	19-10-2016	

141	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	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	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	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	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	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	<u>regulated</u>	11-07-2016
147	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	<u>regulated</u>	11-07-2016
148	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)	<u>regulated</u>	11-07-2016
149	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	<u>Not regulated</u>	11-07-2016
150	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	<u>a) regulated</u> <u>b) not regulated</u>	16-11-2016

151	M/s. Goldwin Medicare Ltd., 101/102 vailankanni towers, A wing, Mari Nagar Off., Senapati Bapat Marg, Mahim (W), Mumbai - 400016	Trancutaneous 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	<u>Not regulated</u>	29-11-2016
152	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	<u>Not regulated</u>	29-11-2016
153	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	<u>Not regulated</u>	29-11-2016

2015 Database

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 Appartment 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 measures 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 injecto intended to deliver the fluid volumes either intramuscularly (IM) of 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 Therapeutix 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 extenal 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 Compund, Western Express Highways, Goregaon Tal: Goregaon (East), Mumbai	Pix L® and Pix'L® + 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 deposties of hyaluronic acid for facial tissue augmentattion.	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 presure cuffs, stechsscope, probes, thermometer, telemedcare 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 for 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 cooperative 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 reaction 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 pediatric 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	Merigrft 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 sinle use, disposable, sterile catheter for the purpose of examination, test or analysisonly 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 terile, 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, Thaltej, Ahemedabad - 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-invasice dermatological aesthetic tratment to lift eyebrow, lax submental and neck tissue	Not Regulated	29.04.2015
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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
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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
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36		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		
	29/Misc./3/2015-DC (82)				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 contained closure system for packing and installation of vaccines and potentially oral drugs	Not Regulated	29.04.2015
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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
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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
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40	29/Misc./3/2015-DC (72)	M/s. Observe Design Pvt. Ltd., Level-3, C-28, Malviya Nagar, New Delhi-110017	Sakshid- Hand Sanitizer Dispenser	Hand sanitizer Distepnser (without any disinfectant or sanitizer) which dispenses hand sanitizer using a mechanical or an electroniv mechanism	Not Regulated	05.05.2015
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41		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		
	29/Misc./3/2015-DC (75)				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
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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
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44		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		
	29/Misc./3/2015-DC (71)				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
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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
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47		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).		
	29/Misc./3/2015-DC (96)				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
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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 treatment of menorrhagia (excessive uterine bleeding) due to benign causes in premenopausal women for whom child bearing is complete	Not Regulated	18.05.2015
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50		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
	29/Misc./3/2015-DC (118)					

51	29/Misc./3/2015-DC (104)	M/s. Emcure Pharmaceuticals Limited, T-184, M.I.D.C. Bhosari, Pune-411026	Histidine-Tryptophan-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
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52		M/s. Ortho Prime, 470, Jawahar Marg Siyaganj, Indore-452007	Fiberglass Orthopedic Tape	used as a casting tape in case of treatment of fractures		
	29/Misc./3/2015-DC (119)				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
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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
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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 treatment of menorrhagia (excessive uterine bleeding) due to benign causes in premenopausal women for whom child bearing is complete	Not Regulated	09.06.2015
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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 adjust 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
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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
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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
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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	Pix'L® and Pix'L® + cannulas	there is no provision for import of device/drug for demo purpose	19.06.2015
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60	29/Misc./3/2015-DC (162)	M/s. Prowin Health Technologies Pvt. Ltd., B-18, 1st Floor, Vengal Rao Nagar, Opp Post Office, S. R. Nagar, Hyderabad - 500038	Smart Coat (Nano Titanium Dioxide)	The product smart coat contains n-type semiconductor photo-catalyst, as an active ingredient which are nano-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
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61		M/s. Lakshmi Life Sciences Ltd., 3/284 A, Sular Railway Feeder Road, Kurumbapalayam, M.G. pudur (PO), Coimbatore-641406			
	29/Misc./3/2015-DC (143)		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
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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
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64	29/Misc./3/2015-DC (152)	M/s. Sahaj Regenerative Cell Therapeutics LLP, 13/2, South Tukoganj, Indore, madhya Pradesh	Cole-Parmer (Ultrasonic Processors)	which is an equipment for homogenisation of tissue in laboratory	Not Regulated	03.07.2015
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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
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66	29/Misc./3/2015-DC (153)	m/s. Creative Resposable 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
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67		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			
	29/Misc./3/2015-DC (158)					
				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
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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
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70		M/s. Wealth Taxi Technology Pvt. Ltd., 24/4818, First Floor, Prahlaad Street, Ansari Road, Daryaganj, new Delhi-110002	iRemeber (A Smart Pill Organizer)		Not Regulated	17.07.2015
	29/Misc./3/2015-DC (150)					

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
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72	29/Misc./3/2015-DC (79)	M/s. CareFusion, 22745 Savi Ranch Parkway, Yorba Linda CA 92887-4668, USA	AVEA Ventilator care products	<ol style="list-style-type: none"> 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
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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 mildy 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
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74	29/Misc./3/2015-DC (68)	<p>M/s. Krupa Medix, 3/37, thirumangal Alwar Street, NH-1, Maraimalai Nagar, tamil nadu pin- 603209</p> <p>M/s. Corions India Pvt. Ltd., No5, Sri Krishna Nagar Annexe, maaduravoyal, chennai- 600095</p>	Orthopaedics External Fixation Products	used in infected non-unions of fractures which need correction and for the boe deformities and bone lengthening procedures	Not Regulated	29.07.2015 12.06.2012
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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
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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
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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 Hybodermic Needled		Regulated	03.08.2015
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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
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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
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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
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81		M/s. Aramex trading Co., 9-ashok Nagar, Lucknow, Uttar Pradesh	Fluor Gel			
	29/Misc./3/2015-DC (177)				Regulated	04.08.2015
				indicated for the prevention (Prophylaxix) of caries		

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
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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 ot collect the umbilical cord blood from umbilical cord during placental delivery of the baby	Not Regulated	12.08.2015
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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
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85		M/s. Joseph Lesile & Co. LLP, Leslico House, 3rd Floor, Pro. V. s. Agashe Rd., Dadar-West, Mumbai-400028	Water Gel Based Blankets			
	29/Misc./3/2015-DC(181)				Not Regulated	25.08.2015
				used as a body wrap to extinguish fires and to cool and moisten burns		

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
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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
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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
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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
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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
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91		M/s. UE Marketing Pvt. Ltd., A-102, Universal Paradise, Nanda Patkar Road, Vile Parle (East), Mumbai-400057	iBrest Exam			
	29/Misc./3/2015-DC(204)				Not Regulated	03.09.2015
				which is a Breast lesion documentation system		

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 surgery	Not Regulated	03.09.2015
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93		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			
	29/Misc./3/2015-DC(158)			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
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95		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
	29/Misc./3/2015-DC(142)					

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
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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 Curettes 7. Micro Surgical Scalpels	Not Regulated	21.09.2015
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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 applicaton of the skin	Not Regulated	29.09.2015
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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
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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
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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
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102		M/s. Dr. Schumacher India Pvt. Ltd., 2A, 2nd Floor, 164, M.G.Road, Pune-411001	Cleanisept Wipes Maxi			
	29/Misc./3/2015-DC(217)			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		M/s. Utanco India, 13, tarun enclave, near pushpanjali, pitam pura, delhi-110034	Orthopaedic casting tapes & splint			
	29/Misc./3/2015-DC(219)			intended for use in the construction of orthopaedic casts, temporary immobilization of fractures, sprains and strains	Regulated	06.10.2015

104		M/s. Sceptre Chemicals Inc., House no. 8-A, 2nd Floor, Siri Nagar Colony, Near Shiva Mandir, Delhi-110052	Citric Acid Solution (Disinfectant)			
	29/Misc./3/2015-DC(228)				Regulated	06.10.2015
				used for disinfection of hemodialysis machine		

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 Acie 17.5 mg + Lidocaine hydrochloride 3 mg (juvederm VOLIFT with Lidocaine) concentration	Not Regulated	06.10.2015
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106		M/s. Delhi Eye Zone Pvt. Ltd., D-114, (G.F.), lajpat nagar-I, New Delhi-110024	Ferrara Ring- an intraconeal Implants			
	29/Misc./3/2014-DC(125)			used for correction of pathological tissue deformities of the fornea	Regulated	13.10.2015

107		M/s. Care Group India, A unit of polymer technologies INTL, Block no. 310, village sim of dabhasa, Ta Padra, Dist. Vadodara- 391440	concal inlay			
	29/Misc./3/2014-DC(125)			used for improving the depth of focus by cutting the unnecessary light entering in the eye	Regulated	13.10.2015

108		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			
	29/Misc./3/2014-DC(125)			indicated to improve near vision in adult presbyopic subjects	Regulated	13.10.2015

109		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			
	29/Misc./3/2015-DC(221)			used for sterilization on non-surgically invasive medical devices such as gastroscope of 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		M/s. Johnson & Johnson Pvt. Ltd., LBS Marg, Mulund (West), Mumbai-400080	Temporary Cardiac Pacing Wire			
	29/Misc./3/2015-DC(223)				Not Regulated	14.10.2015
				intended for use in temporary cardiac pacing or monitoring		

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
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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	<ol style="list-style-type: none"> 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) 	<ol style="list-style-type: none"> 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, ointments and other primary dressings. 6. wound dressing for ulcers 	Regulated	09.11.2015
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113		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			
	29/Misc./3/2015-DC(120)				Regulated	09.11.2015

114		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			
	29/Misc./3/2015-DC(236)				Not Regulated	09.11.2015
				used in dentistry		

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
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116		M/s. Paseca Healthcare LLP., Factory: K-68, Sector-3, Bawana Industrial Area, new Delhi - 110039				
	29/Misc./3/2015-DC(239)				Regulated	20.11.2015
			1. Hydrocolloid Dressing with Foam 2. Dressing Wound 3. Tranparent wound medicated 4. polymen dressing 5. pressing post op medicated			

117		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			
	29/Misc./3/2015-DC(232)				Regulated	20.11.2015
				used to collect blood for testing		

118		M/s. Dr. Schumacher India Pvt. Ltd., 2A, 2nd Floor, 164, M.G.Road, Pune-411001	Cleanisept Wipes Maxi			
	29/Misc./3/2015-DC(217)			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 facilitates monitoring and tracking of the infants or babies temperture	Not Regulated	17.12.2015
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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, Valluvaserry, Temple Road, N.F. Gate, Tripunithura P.O. Cochin-682301	woodcast Products	are devices indicatd 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
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2014 Database

S. NO.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	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	<u>Not Regulated</u>	03-01-2014
2	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	<u>Not Regulated</u>	15-01-2014
3	M/s. Becton Dickinson India Pvt. Ltd., No. 34 Assisi Nagar, West Thottam, Madhavram, Chennai 51	1. BD Vacutainer Blood Transfer Device (without needle)		<u>Not Regulated</u>	15-01-2014
4	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	<u>Regulated</u>	15-01-2014
5	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.	<u>Regulated</u>	15-01-2014

6	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 rhytm measurement (ECG) at a touch of their fingers with clinical precision providing remote health monitoring solution	<u>Not Regulated</u>	15-01-2014	
7	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	<u>Regulated</u>	15-01-2014	
8	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		<u>Not Regulated</u>	15-01-2014	
9	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	<u>Regulated</u>	20-01-2014	

10	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	<u>Regulated</u>	21-01-2014	
11	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>	21-01-2014	
12	M/s. Molnlycke Health Care India Private Limited 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>	21-01-2014	
		2. Barrier Surgical Staff Clothing, 3. Barrier Supplementaries (Stand Covers, Table Covers, Pouches, Equipment Drapes) 4. Barrier Easywarm Blanket		<u>Not Regulated</u>		
13	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>	21-01-2014	

14	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>	28-01- 2014	
15	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>	28-01- 2014	
16	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>	28-01- 2014	
17	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>	25-02- 2014	
18	M/s. Viridis BioPharma Pvt. Ltd., 6/10 Jogani Industrial Complex, V.N. Purav Marg, Chunabhatti, Mumbai 400022	1. Dental Sealant		<u>Regulated</u>	25-02- 2014	
19	M/s. Surgimedik Healthcare, 1B- 904, Green Acres, Lokhandwala Complex, Andher (W), Mumbai- 400053	1. Dexell	Use for Vesicoureteral Reflux (VUR)	<u>Regulated</u>	07-03- 2014	
20	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>	23-04- 2014	

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>	30-04- 2014	
22	M/s. Surgimedik Healthcare India Pvt. Ltd., Surgimedik House, 53 CD, Kandivali Co-operative Industrial Estate, Charkop, Kankivali West, Mumbai-40067	1. Guidewires		<u>Regulated</u>	30-04- 2014	
23	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 refracory to antiepileptic medications	<u>Not Regulated</u>	30-04- 2014	
24	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	<u>Regulated</u>	02-05- 2014	
25	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	<u>Regulated</u>	05-05- 2014	
26	M/s. Nanz Med Scinces Pharma (P)Ltd., Rampur Ghat, Paonta Sahib, District Sirmour, H.P	1. Isopropyl Alcohol/ Pre Injection Swabs		<u>Regulated</u>	06-05- 2014	

27	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	<u>Regulated</u>	06-05- 2014	
28	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	<u>Not Regulated</u>	15-05- 2014	
29	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)		<u>Regulated</u>	21-05- 2014	
30	M/s. Abbott Healthcare Pvt. Ltd., Corporate Park Sion Trpmbay Road, Mumbai-400071	1. OROSOL spray	Intended as an adjuvant in the management of chemo & radio therpy including oral mucositis or ulcer of the oral mucosa alongwith standard treatment	<u>Regulated</u>	30-05- 2014	

31	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		<u>Regulated</u>	04-06-2014	
32	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>	04-06-2014	
33	Mr. S S Bhatia Col, Dy. Commandant, Armed Forces Medical Stores Depot, Delhi Cantt-10	1. Ligating Clips		<u>Regulated</u>	06-06-2014	
34	M/s. Medilinks Inc., 03, Noble House, Gr. Flr, Dr. Batliawala Labe Parel, Mumbai-400012	1. External Breast Prosthesis Maxima		<u>Not Regulated</u>	09-06-2014	
35	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>	09-06-2014	
36	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>	25-06-2014	
37	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>	04-07-2014	

2013 Database

S. NO.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue	
1	M/s. Labtech Disposablse 406-Shefali Shopping Centre, Paldi Char Rasta, Ahmedabad-6	1. Blood Collection Tubes		<u>Not Regulated</u>	03-01-2013	
2	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>	08-01-2013	
3	M/s. Bear Medic Corporation, Yushima 2-31-24, Bunkyok-Ku, Tokyo 113-0034 Japan	1. Disposable Micro Vascular Clip		<u>Not Regulated</u>	08-01-2013	
4	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>	08-01-2013	
5	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>	08-01-2013	
6	M/s. Chadha & Co., Advocates & Legal Consultants, S-327, Greater Kailash-II, New Delhi-110048	1. Prevena™ Incision Management System		<u>Regulated</u>	19-02-2013	

7	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>	19-02-2013	
8	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>	26-02-2013	
9	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>	26-02-2013	
10	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>	06-03-2013	
11	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 Distinfectant		<u>Regulated</u>	06-03-2013	
12	M/s. Stryker Indai Pvt. Ltd., C-5, SDA, Commercial Complex New Delhi-110016	1. Transcend Guidewires		<u>Regulated</u>	06-03-2013	
13	M/s. Bell Surigcal, Unit No. 68, Part A, Municipal Industrial Estate, Gandhi Nagar, Worlil, Mumbai-400018	1. Casting Tape intended to fix broken or dislocated bone		<u>Regulated</u>	06-03-2013	

14	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>	02-04-2013	
15	M/s. Abbott Healthcare Pvt. Ltd., 4, Corporate Park, Sion Trombay Road, Mumbai-400071, India	1. Acetium Capsule		<u>Regulated</u>	05-04-2013	
16	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>	05-04-2013	
17	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>	05-04-2013	
18	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>	09-04-2013	
19	M/s. Allied Healthcare India 3, Arumugam Street, Anna Salai, Chennai-600002	1. Enteral Feeding set for giving nutrition for patients		<u>Regulated</u>	09-04-2013	
20	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>	23-04-2013	
21	M/s. Sterile Medical Apps. Inc., A-140/1, Okhla Industrial Area, Phase-II, New Delhi-20	1. Surgical Dressing		<u>Regulated</u>	23-04-2013	
22	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>	23-04-2013	

23	M/s. Guerbet India Liaison Office 422, Level 4, Augusta Point Sector 53, Golf Course Road, Gurgaon-122002	1. Lipiodal		<u>Regulated</u>	23-04-2013	
24	M/s. Emergo (India) Consulting Pvt. Ltd., 8/1, Vasavi Colony, kaka Guda, Secunderabad, Andhra Pradesh-500009	1. Gutta Percha		<u>Not Regulated</u>	29-04-2013	
25	M/s. Litejoy International Private Limited, S-289, Ground Floor, Greater Kailash-I, New Delhi- 110048	1. Disposable Electronic Cigarettes		<u>Not Regulated</u>	30-04-2013	
26	M/s. Intas Medi Devices Limited, 9th Floor, Premier House-1, S.G Highway, Bodakdev Ahmedabad- 380054	1. Guidewires		<u>Regulated</u>	30-04-2013	
27	M/s. Ecobase, Lieserhoferstraße 7-9851. Lieserbrucka Austria	1. Activated Zeolite		<u>Regulated</u>	30-04-2013	
28	M/s. GlaxoSmithKline Asia Pvt. Ltd., Plot No. 67, Sector-32, Gurgaon-122001, Hayana	1. Denture Cleansing Cream		<u>Not Regulated</u>	30-04-2013	
29	M/s. GlaxoSmithKline Asia Pvt. Ltd., Plot No. 67, Sector-32, Gurgaon-122001, Hayana	1. Denture Cleansing Tablets		<u>Regulated</u>	30-04-2013	
30	M/s. Terra India, 5/20, Punjabi Bagh Extn. New Delhi-110026	1. Health Worker Bag and Vaccum Extractor		<u>Regulated</u>	01-05-2013	
31	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)		<u>Not Regulated</u>	01-05-2013	

32	M/s. India Medtronic Pvt. Ltd., A-16, Mohan Co-operative Industrial Estate Ltd., Ground Floor, Mathura Road, New Delhi-110044	1. Meroxel Hemox Sponges		<u>Regulated</u>	08-05-2013	
33	M/s. Meril Endosurgery Pvt. Ltd., Survey No. 135/2/B, Bilakhia House Muktanand Marg, Chala, Vapi-396191, Gujarat	1. Cartridge/Pins		<u>Regulated</u>	09-05-2013	
34	M/s. Meril Endosurgery Pvt. Ltd., Survey No. 135/2/B, Bilakhia House Muktanand Marg, Chala, Vapi-396191, Gujarat	1. Staplers (Instrument)		<u>Not Regulated</u>	09-05-2013	
35	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)		<u>Regulated</u>	09-05-2013	
36	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		<u>Not Regulated</u>	09-05-2013	
37	M/s. Vipro Lifesciences, 402-403, Sarthik-II, Oppt. Rajpath Club, S.G Road, Ahmedabad	1. Condoms		<u>Regulated</u>	21-05-2013	
38	M/s. Stryker Indai Pvt. Ltd., C-5, SDA, Commercial Complex New Delhi-110016	1. Trevo Retrievers		<u>Regulated</u>	21-05-2013	
39	M/s. Vinvish Technologies Pvt. Ltd., C-16, Level C, Thejaswini Building, Technopark, Trivandrum, Kerala-695581	1. Photo Dynamic Therapy Laser system		<u>Not Regulated</u>	21-05-2013	

40	M/s. Zest Othocare Pvt. Ltd., 48, 1st Floor, Sardar Nagar Society, Sumul Diary Road, Surat-395008	1. CAST O LITE		<u>Regulated</u>	03-06-2013	
41	M/s. Taneermedico A/S DTU Sciences Park, Agern Alle 3, DK-2970 Horsholm, Denmark	1. Asonor		<u>Regulated</u>	04-06-2013	
42	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		<u>Regulated</u>	04-06-2013	
43	M/s. Intech Safety Pvt. Ltd., 83 & 84 Chanditala Main Road, Kolkata-700053	1. Self Generating Oxygen Type Chemical Self Rescuer (SCSR)		<u>Regulated</u>	04-06-2013	
44	M/s. South India Surgical Co. Ltd., #117/65, Wallajah Road, Chennai-600002	1. Capsule Endoscope		<u>Not Regulated</u>	04-06-2013	
45	M/s. B. Braun Medical (India) Pvt. Ltd., III Floor, 23-A, Shivaji Marg, Najafgarh Road New Delhi-110015	1. Sol-Cart B		<u>Regulated</u>	04-06-2013	
46	M/s. Emergo (India) Consulting Pvt. Ltd., 8/1, Vasavi Colony, kaka Guda, Secunderabad, Andhra Pradesh-500009	1. Mix2Vial Transfer Devices		<u>Regulated</u>	04-06-2013	
47	M/s. Kamuk Life, 01 Darshan Enclave, Bopal-Ghuma Road, Ghuma-380058	1. Magical Granule Patch		<u>Not Regulated</u>	11-06-2013	

48	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		<u>Regulated</u>	14-06-2013	
49	M/s. Greatlinx Impex Pvt. Ltd., 104, Vanchinad Building, Kaloor, Cochin, Kerala, 682017	1. Silicone Gel Ointment and Silicone Sheet		<u>Regulated</u>	18-06-2013	
50	M/s. Benson Medical Equipments (India) Pvt. Ltd., New Delhi	1. Medical Equipment's		<u>Not Regulated</u>	03-07-2013	
51	M/s. Q Pharm Cousulting India # 26, Hi-Rise Colony, Phase-II, Nizampet, Hyderabad-500090	1. Personal Lubricant, "PROBE"		<u>Regulated</u>	09-07-2013	
52	M/s. HLL Lifecare Limited, A Govt of India Enterprises, HLL Bhavan, Poojappura, Thiruvananthapuram-695012	1. Empty PVC Bags		<u>Not Regulated</u>	09-07-2013	
53	M/s. Gambro India Pvt. Ltd., No. 5, Sixth Floor, Crown Court No. 34/New no. 128, Cathedral Road Chennai-600086	1. Bicart		<u>Regulated</u>	15-07-2013	
54	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		<u>Regulated</u>	19-07-2013	
55	M/s. Nextgen Solution Pvt. Ltd., E-501, Sunflower Society, Gundecha Colony, Thakur Villiage, Kandivali (E), Mumbai-400101	1. Double Pump RF Day Cassette & Double Pump RF Patients Cassette		<u>Not Regulated</u>	19-07-2013	

56	M/s. Sterimed Inc., Peringannur, Peringode, Pattambi-679535 Palakkad, Kerela, India	1. Sterilization monitoring		<u>Not Regulated</u>	23-07-2013	
57	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		<u>Regulated</u>	06-08-2013	
58	Mr. Pramod Kumar, Foreign Trade Development Officer, Ministry of Commerace 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, Fractute Aids, Pelvic Traction Kit		<u>Not Regulated</u>	06-08-2013	
59	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		<u>Regulated</u>	06-08-2013	
60	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)		<u>Not Regulated</u>	06-08-2013	

61	M/s. Kimberly-Clark Hygiene Products Pvt. Ltd., Survey No. 279, Rasoni 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		<u>Not Regulated</u>	06-08-2013	
62	M/s. Covidien Healthcare India Pvt. Ltd., 10th Floor, Building No. 9 B, DLF Cyber City, Phase-3, Gurgaon-122002, Haryana	1. Surgisleeve		<u>Not Regulated</u>	06-08-2013	
63	M/s. Becton Dickinson India Pvt. Ltd., 5th Floor, Signature Tower B, South City I, Gurgaon-12201, Haryana, India	1. BD Sentry Safety Lancet		<u>Regulated</u>	05-08-2013	
64	M/s. India Sani Chem C-28, Pushpanjali Farms, Bijwasan, New Delhi-110061	1. Echo-Clean PRO Purge		<u>Not Regulated</u>	12-08-2013	
65	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		<u>Regulated</u>	27-08-2013	
66	M/s. Zest Othocare Pvt. Ltd., 48, 1st Floor, Sardar Nagar Society, Sumul Diary Road, Surat-395008	1. ALTOCAST		<u>Regulated</u>	03-09-2013	
67	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 Cannula		<u>Not Regulated</u>	03-09-2013	

68	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)		<u>Regulated</u>	04-09-2013	
69	M/s. Meril Endosurgery Pvt. Ltd., Survey No. 135/2/B, Bilakhia House Muktanand Marg, Chala, Vapi-396191, Gujarat	1. Surgical Trocar		<u>Not Regulated</u>	04-09-2013	
70	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 spread of certain bacteria	<u>Regulated</u>	10-09-2013	
71	M/s. Rekha Production Pvt. Ltd., & SGS Sciences, Aditya Enclave, Flat #G11, Kanchna Junga 'D' Block, Ameerpet, Hyderabad.	1. Anti-radiation Chip		<u>Not Regulated</u>	10-09-2013	
72	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)		<u>Not Regulated</u>	25-09-2013	
73	M/s. Faith Innovation, E-107, Lajpat Nagar-I, New Delhi-110024	1. Sterigen Disinfectant Generation System		<u>Not Regulated</u>	14-10-2013	

		<p>Super Oxidized solution/Sterigen solution containing salts like Sodium Hypochlorite, Hypochlorous acid, Hygreogen peroxide, Ozone, Cholorine dioxide, Sodium Hydroxide, Sodium Carbonate and Sodium Chloride</p>	Used as a disinfectant	<u>Regulated</u>		-
74	M/s. Chitrarath, 5 Darshana Bhawan, HR/62A, Sohan Lal Marg, Pul Pahladpur, New Delhi-110044	1. Sureseal (Self activatin Pressure Bandage)		<u>Regulated</u>	21-10-2013	

75	<p>M/s. 3M India Ltd., Plot No. 48-51, Electroics City, Hosur Road, Bangalore-560100</p>	<ol style="list-style-type: none"> 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. 	<ol style="list-style-type: none"> 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 solidify the adhesive bonding products 6. Elastics or rubberbands used to hold the wires to the brackets whille moving the teeth. 7.Headstraps made of elastic or plastic to take support outside the mouth for support to move the teeth 8. Various instruments to fix and remove brackets, wires and elastics for tooth movement. 	<p><u>Not Regulated</u></p>	<p>21-10-2013</p>	
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76	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 the growth of the bacteria	<u>Regulated</u>	22-10-2013	
77	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 of closed wounds and scars	<u>Regulated</u>	22-10-2013	
78	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>	12-11-2013	
79	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 Stem Cells and Cord Blood Stem Cell	<u>Regulated</u>	19-11-2013	
80	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 ultrasound for in situ tumor ablation without surgery	<u>Not Regulated</u>	19-11-2013	

81	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 to inflate the lungs of an unconscious person who is not breathing	<u>Not Regulated</u>	26-11-2013	
82	M/s. 3M India Ltd., Plot No. 48-51, Electroics City, Hosur Road, Bangalore-560100	1. IV Securement Dressings		<u>Regulated</u>	26-11-2013	
83	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>	26-11-2013	
84	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>	06-12-2013	
85	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>	11-12-2013	
86	M/s. M.J. Medical Devices Private Limited, 706, Rajgir Sadan, 7th Floor, Lami Baug, Mumbai-400022	1. Flexiseq	Treatment of pain associated with osteoarthritis	<u>Regulated</u>	16-12-2013	

87	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 form external dust, bacteria, water contamination etc.	<u>Regulated</u>	27-12-2013	
88	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 Catheter, Central Catheters, Pediatic catherters.	<u>Not Regulated</u>	27-12-2013	
89	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 current at the site of the tumor	<u>Not Regulated</u>	27-12-2013	

2012 Database

S. NO.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	M/s. Beauvana Biotech Pvt. Ltd., 6/7 A, Selva Ratna Vinayagar Ave, Cart Tract Road, Velchery, Chennai-600042	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>	03-01-2012
2	M/s. Beauvana Biotech Pvt. Ltd., 6/7 A, Selva Ratna Vinayagar Ave, Cart Tract Road, Velchery, Chennai-600042	1. Bioring Gastric Lap Brand		<u>Regulated</u>	03-01-2012

3	The Director, Directorate of Food & Drugs Admn., Old I.P.H.B. Complex, Altinho, Panji-Goa	<ol style="list-style-type: none"> 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 3. Extension set, 2 needle-free valves, spin male luer lock 4. Needle Free Valve 5. 13MM Vial access device 6. 20mm Vial access device 7. Bag spike 8. Bag spike with needle free cjeck valve 9. Smallbore extension set, 1 needle-free valve, Spin male luer lock 10. Texium® closed mal luer with female cap. 11. Smallbore extension set, J-Loop, 1 needle-free valve, spin male luer lock 12. 3 way stopcock 2 SmartSite connector 13. 8280 vial access device vented SmartSite valve 14. Extension set, 2 way, 2 SmartSite valve 7CM 15. Extension Set, 3 way, 3 SmartSite valve 7CM 16. Stopcock, 3 way with SmartSite valve 		<u>Regulated</u>	03-01-2012
4	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>	17-01-2012

5	M/s. Medicaid Agencies, 204, Shivlok House-II, Karmapura Comm. Complex, New Delhi-110015	1. Bone Injection Gun		<u>Regulated</u>	24-01-2012
6	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, Near Picket, Secunderabad- 500009 (A.P)	1. Spiro PD	Used for measurement of air flow & volume of lungs	<u>Not Regulated</u>	24-01-2012
7	M/s. A. B. Dental Devinces Ltd., Park Hanada, 3 Habosem St. Ashdod Israel	1. Dental Implant and Abutments		<u>Regulated</u>	24-01-2012
8	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 human gametes or embryos for the intra vaginal culture	<u>Not Regulated</u>	31-01-2012
9	M/s. Indian Hygiene Products Co., 176, Bara Bazar, Kolkata-6	1. Ribbel Ultra Comfort Adult Diaper		<u>Not Regulated</u>	13-02-2012
10	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 Intraspinal Dura substitution procedures	<u>Regulated</u>	14-02-2012
11	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>	14-02-2012
12	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>	14-02-2012

13	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>	27-02- 2013
14	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>	01-03- 2012
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>	01-03- 2013
16	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>	01-03- 2012
17	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>	01-03- 2012
18	M/s. Buoyant Medicos, 47/12, LGF, Old Rajinder Nagar, New Delhi	1. Hematrix- acive patch wound dressing for immediate Haemostasis	Used on external wounds to stop even severe arterial or venous bleeding	<u>Regulated</u>	01-03- 2012
19	M/s. Nirma Limited, Nirma House, Ashram Road, Ahmedabad-380009	1. Non sterile Bulk Syringes		<u>Regulated</u>	01-03- 2012
20	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>	01-03- 2012
21	M/s. Delhi Ey Zone Pvt. Ltd., D- 114, (G.F.), Lajpat Nagar-I, New Delhi-110024	1. Labtician Retinal Implants	Used in the treatment of retinal detachments	<u>Not Regulated</u>	01-03- 2012

22	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>	06-03-2012
23	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>	06-03-2012
24	Sh. Samir Sinha, Foreign Trade Development Officer, Ministry of Commerace and Industry, DGFT, Udyog Bhavan, New Delhi	1. Gauze Rolls	Used for Wound dressings (Surgical Dressings)	<u>Regulated</u>	06-03-2013
25	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>	09-03-2013
26	M/s. 3 M India Limited, Plot Nos. 48-51, Electronics City, Hosur Road, Bangalore-560100	1. 3M Ranger Blood	Dissposable I.V. Adminstration set (Ranger lood)	<u>Regulated</u>	09-03-2013
27	M/s. Medi Globe Systems, # 22, Pandaram Street, Purasaiwakkam, Chennai- 600007	1. Tube Holder and Vacuum Tube		<u>Not Regulated</u>	29-03-2012
28	M/s. Medi Globe Systems, # 22, Pandaram Street, Purasaiwakkam, Chennai- 600007	1. Double Ended Needle (Multi sample Needle)		<u>Regulated</u>	29-03-2012
29	M/s. Medihaxe 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>	03-04-2012

30	M/s. 3 M India Limited, Plot Nos. 48-51, Electronics City, Hosur Road, Bangalore-560100	1. Scotchast Premium Casting Tape		<u>Regulated</u>	03-04-2012
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>	03-04-2012
32	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>	03-04-2012
33	M/s. In Vitro Medical Solutions (P) Ltd., E-291, Sarita Vihar, New Delhil-110076	1. Vacuum & non vacuum tubes, Lencet Tourniquets and Needle Holder		<u>Not Regulated</u>	04-04-2012
34	M/s. In Vitro Medical Solutions (P) Ltd., E-291, Sarita Vihar, New Delhil-110076	1. Multi Sample Needle (Pen Type and Butterfly Type)		<u>Regulated</u>	04-04-2012
35	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>	04-04-2012
36	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>	10-04-2012

37	M/s. UP Dental Products Pvt. Ltd., 107, 1st Floor, Sai Commercial Centre, Mumbai - 400088	<ol style="list-style-type: none"> 1. Porcelain Etch & Silane 2. Sable Seek 3. VALO 4. Sof-Tray Classic Sheets 5. Ultracal 6. Ultra-blend plus 7. File-Eze 	<ol style="list-style-type: none"> 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>	10-04-2012
38	M/s. Varian Medical Systems India Software Pvt. Ltd., Tower XL, Level 7, Cybercity Magarpatta, Hadapsar, Pune-411013	<ol style="list-style-type: none"> 1. Calypso 	Used to detect cancer organ movement during radiation treatment	<u>Not Regulated</u>	10-04-2012
39	M/s. SkinCare Surgipharma Pvt. Ltd., Shop No. 7, Salamat Mansion (Opp. Ravindra Natya Mandir), Sayani Road, Prabhadevi, Mumbai- 400025	<ol style="list-style-type: none"> 1. Oragrafts (Bone Graft) 2. RediGrafts (Bone Graft) 3. FlexiGrafts (Tissue Graft) 		<u>Not Regulated</u>	10-04-2013
40	M/s. Arun & Co., 601/A & 602/B Polaris, off Marol Maroshi Road, Marol, Andheri (East), Mumbai-400059	<ol style="list-style-type: none"> 1. Diagnostic Enzymes- Panicillinase 2. B-Lactamase 	Used in Laboratory	<u>Not Regulated</u>	17-04-2012
41	M/s. ClinTech India, Plot # 222, Sabari Aangan, 11th Road, Chembur, Mumbai-400071	<ol style="list-style-type: none"> 1. Hemo Rite 	Used is for treatment of hemorrhoids by Cryotherapy	<u>Not Regulated</u>	17-04-2012

42	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, 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>	17-04-2012
43	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, Near Picket, Secunderabad- 500009 (A.P)	2. Epiflo® Transdermal Continuous oxygen therapy	Intended to deliver pure oxygen to the wounds	<u>Not Regulated</u>	17-04-2012
44	M/s. Vascular Concepts Ltd., 7C, Doddaballapur Industrial Estate, Doddaballapur, Bangalore- 561203	1. Pronova CC-Sirolimus Eluting Stent		<u>Regulated</u>	18-04-2012
45	M/s. Vascular Concepts Ltd., 7C, Doddaballapur Industrial Estate, Doddaballapur, Bangalore- 561203	1. Pronova XR-Sirolimus Eluting Stent		<u>Regulated</u>	18-04-2012
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>	24-04-2012
47	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>	24-04-2012

48	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>	24-04-2012
49	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>	26-04-2012
50	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>	26-04-2012
51	M/s. Care Fusion, Tower D, Second Level, DLF IT Park, Kishangarh, Chandigarh	1. SmartSite	Used as a self sealing connector	<u>Regulated</u>	26-04-2012
52	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>	26-04-2012
53	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>	01-05-2012
54	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>	01-05-2012

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>	01-05-2012
56	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>	01-05-2012
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>	03-05-2012
58	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>	08-05-2012
59	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>	08-05-2012
60	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>	15-05-2012
61	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>	23-05-2012
62	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>	23-05-2012

63	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>	23-05-2012
64	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>	23-05-2012
65	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>	23-05-2012
66	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>Regualted</u>	23-05-2012
67	M/s. 3 M India Limited, Plot Nos. 48-51, Electronics City, Hosur Road, Bangalore-560100	1. Tissue Adhesive for animal use		<u>Regualted</u>	23-05-2012
68	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>Regualted</u>	30-05-2012
69	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>Regualted</u>	30-05-2012

70	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>	12-06-2013
71	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>	12-06-2013
72	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>	12-06-2012
73	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>	12-06-2012
74	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>	12-06-2012
75	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>	12-06-2012
76	M/s. Maxlige, New No. 56, Old No. 45/62, 2nd Main, Gabbvipuram Extension, Bangalore-560019	1. Tubing Set for Hemodialysis		<u>Regulated</u>	12-06-2012
77	M/s. Kanam Latex Industries Private Limited, Oppoottil Building, K.K. Road, Kottayam-	1. Surgical Sterile Gloves/ Non Sterile Surgical Gloves		<u>Not Regulated</u>	04-07-2012

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78	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 menstural pain	<u>Regulated</u>	04-07-2012	
79	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>	04-07-2012	
80	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>	11-07-2012	
			Multi sample Needle (Disposable)	<u>Regulated</u>		
81	M/s. Metacure Limited, 22, Victoria Street, Hamilton HM 12, Bermuda	1. Optimizer III A Cardiac Contractility modulation system		<u>Not Regulated</u>	11-07-2012	
82	M/s. Metacure Limited, 22, Victoria Street, Hamilton HM 12, Bermuda	1. Diamond (Tantalus) System		<u>Not Regulated</u>	11-07-2012	
83	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>	11-07-2012	
84	M/s. Adroit Biomed Ltd, 2nd Floor, A-Wing, Balsmruti, Murar Road, Mulund (W), Mumbai-400080	1. respiR8 Monitor		<u>Not Regulated</u>	11-07-2012	
85	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>	11-07-2012	

86	M/s. Harsoria Healthcare Pvt. Ltd., 110-111, Phase -IV, Udyog Vihar, Gurgaon, Haryana-122015	1. Pressure Monitoring Line		<u>Regulated</u>	11-07-2012
87	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>	11-07-2012
88	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>	11-07-2012
89	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>	11-07-2012
90	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>	11-07-2012
91	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>	11-07-2013
92	M/s. BL Lifesciences Pvt. Ltd., A-245, Okhla Industiral Area, Phase-I, New Delhi-110020	1. Pressure Monitoring line and Pressure Monitoring Kits		<u>Regulated</u>	11-07-2012
		2. Cardioplegia, vessel loop, toruniquet kit and Mister Blower		<u>Not Regulated</u>	11-07-2012

93	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>	16-07-2012
			Enflow disposable cartridge with or without extension set- used to connects to the IV Extension Set or any infusion set	<u>Regulated</u>	16-07-2012
94	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>	16-07-2012
95	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>	20-07-2012
96	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>	31-07-2012
97	M/s. Edvego Technologies, No. 41, 2nd Floor, 14th Cross, 18th Main, Padmanabha Nagar, Bangalore-560070	1. Tubing set for Hemodialysis		<u>Regulated</u>	01-08-2012
98	M/s. Stericat Gutstrings (P) Ltd. 169, Sector-4, IMT Manesar, Gurgaon, Haryan-122050	1. Non sterile Sutute Thread		<u>Regulated</u>	01-08-2012

99	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>	08-08-2012
100	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>	03-09-2012
101	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>	07-09-2012
102	M/s. Canary Impex, 221, 2nd Floor, Rajhans Shopping Center, Nr. Baroda Pristage, Vrachha Road, Surat-06	1. Disposable Hemorrhoids Stapler		<u>Regulated</u>	07-09-2012
103	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>	07-09-2012

104	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>	07-09-2012
105	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>	07-09-2012
106	M/s. Gennova Biopharmaceuticals Limited T-184, M.I.D.C, Bhosari, Pune-411026	1. Hypak® Barrels (without needlse), plunger rod and Stoppers		<u>Not Regulated</u>	07-09-2012
107	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>	07-09-2012

108	M/s. S.M Health Care Products Pvt. Ltd., 14/95, 1st Floor, Geeta Colony, Delhi-110031	1. Semi-finished, Non Sterile Products-Catheters/ and sizes, Biopsy products/ Needles 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>	07-09-2012
109	M/s. Totipotent Scientific Product Pvt. Ltd., 857, Udyog Vihar, Phase-V, Gurgaon-122016	1. Umbilical Cord Tissue Transport Tube (Tube with buffered saline only no umbilical cord)		<u>Not Regulated</u>	25-09-2012
110	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>	25-09-2012
111	M/s. Neutron Sugicals Pvt. Ltd. 306, Yusug Bldg, 50/51, V. Nariman Road, Near Akbarally's Fort, Mumbai-400001	1. Ostomy Bags	For collection of wastes form sugical diverted biological system (Colon, ileum, urinary) and certain of stoma	<u>Not Regulated</u>	19-09-2012
112	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>	19-09-2012
		2. Oxygenator		<u>Regulated</u>	

113	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>	19-09-2012
114	M/s. Cyro Healthcare 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, including dogs, cats, horses, hotspots, burns or other irritations of the skin to help keep them clean and dry, and help protect them from infection	<u>Regulated</u>	23-11-2012
115	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 Surgical instruments.	<u>Not Regulated</u>	11-12-2012
116	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, Near Picket, Secunderabad- 500009 (A.P)	1. Vadera KXS System	Which delivers a short burst energy in a predetermined pattern onto human cornea	<u>Not Regulated</u>	11-12-2012
117	M/s. Accredited Consultants Pvt. Ltd., D-29, First Floor, Acharya Niketan, Mayur Vihar Phase-1, Delhi-110091	1. Ostomy Bags	For collection of wastes from surgical diverted biological system (Colon, ileum, urinary) and certain of stoma	<u>Not Regulated</u>	11-12-2012

118	M/s. Lifewatch Technologies Ltd., 2 Perkeris St. P.O. Box-527, Rehovot-76100, Israel	1. Lifewatch V		<u>Not Regulated</u>	13-12-2012
		2. Glucose test strips		<u>Regulated</u>	
119	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>	13-12-2012
120	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>	13-12-2012
121	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>	31-12-2012

2011 Database

S. NO.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	M/s. Embrace, 1902 Divisadero Street, San Francisco, CA 94115, USA	1. EIW 2010-002	Using Embrace Infant in Low birth Weight Neonates	<u>Not Regulated</u>	13-01-2011
2	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		<u>Regulated</u>	31-01-2011
3	M/s. Jindal Medical & Scientific Instruments Company (Pvt.) Ltd., C-53A, Mansarovar Garden, New Delhi-110015	1. Sea Tangle Tents (Laminara Tents) a Cervical Dilator		<u>Not Regulated</u>	31-01-2011
4	M/s. Medicare Products Inc., C-53 A, Mansarovar Garden, New Delhi-110015	1. Sea Tangle Tents (Laminara Tents) a Cervical Dilator		<u>Not Regulated</u>	31-01-2011
5	M/s. Inshitra Medical Pvt. Ltd., 1201, Bldg. No. 15, Indradarshan, Phase II, Near Millat Nagar, Andheri (W), Mumbai-400053	1. Hernia repair implants		<u>Regulated</u>	31-01-2011
6	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		<u>Regulated</u>	31-01-2011

7	M/s. Cardiomedics Inc., 7 Whatney, Suite B, Irvine, CA 92618	1. Cardiasist External Counter Pulsation (ECP) System		<u>Not Regulated</u>	04-02-2011
8	Sh. Ram Chnder, Under Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Shastri Bhawan, New Delhi	1. Adult Diaper		<u>Not Regulated</u>	14-02-2011
9	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		<u>Not Regulated</u>	18-02-2011
10	M/s. Mitra Industries (P) Ltd., 14/4, Delhi-Mathura Road, Faridabad-121003	1. Esophageal stents, Biliary stents, Colorectal Stens, Pyloric/Duodenal stents and Tracheobronchial stent		<u>Regulated</u>	18-02-2011
11	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>	23-02-2011

		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	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>	07-03-2011
13	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>	07-03-2011
14	Dr. Sambhav Shah (M.S. Orthopaedic), 404, Simla House, E Block, Nepensea Road, Mumbai-400036	1. Humazone Machine		<u>Not Regulated</u>	08-03-2011
15	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>	10-03-2011

16	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>	15-03-2011
17	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>	15-03-2011
18	M/s. Truskin Gloves Pvt. LTD., Plot No. 14C, Cochin Special Economic Zone, Kakkanad, Cochin-682037	1. Sterile Surgical Gloves		<u>Not Regulated</u>	06-04-2011
19	Swedish Trade Council, C/o Embassay of Sweden, Nyaya Marg, New Delhi-110021	1. BIP Foley Catheter		<u>Regulated</u>	06-04-2011
20	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>	06-04-2011
21	Sh. Sudhir Kumar, Under Secretary to Government of Inida, Nirman Bhavan, New Delhi	1. KKT Treatment Technology		<u>Not Regulated</u>	18-04-2011
22	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>	18-04-2011
		2. Sensor		<u>Regulated</u>	

23	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>	18-04-2011
24	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>	18-04-2011
25	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>	25-04-2011
26	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>	25-04-2011
27	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>	26-04-2011
28	Dr. N.K. Agarwal Deputy Director Gernal (Ophth), DGHS Nirman Bhawan, New Delhi	1. Contact Lens Cleaning Solution		<u>Not Regulated</u>	05-05-2011

29	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>	30-05-2011
30	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>	01-06-2011
31	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>	07-06-2011
32	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>	09-06-2011
33	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>	09-06-2011
34	Mr. Akash Chauhan, Senior Associate, India Law Officers, D-19, (GF), South Extension-I, New Delhi-49	1. Doc Laser		<u>Not Regulated</u>	09-06-2011

35	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		<u>Not Regulated</u>	21-06-2011
36	M/s. Friends Consolidation Ltd., #8-2- 293/82/A/281-O, Road # 10B, Gayatri Hills, Jubilee Hills, Hyderabad- 500033	1. Haemostatic Pad		<u>Regulated</u>	21-06-2011
37	M/s. G.S.T. Corporation, B-13, Okhla Industiral Area, Phase II, New Delhi-20	1. Veusable Veterinary Needles		<u>Regulated</u>	22-06-2011
38	M/s. B. Braun Medical (India) Pvt. Ltd., III Floor, 23-A, Shivaji Marg, Najafgarh Road New Delhi-110015	1. Intravenous Infusion Administraion Sets		<u>Regulated</u>	05-07-2011
39	S-Three Sales Intl. Pvt. Ltd., D-9, Jangpura Extension, New Delhi- 110014	1. Safest Blood Samplling System		<u>Regulated</u>	05-07-2011
40	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		<u>Not Regulated</u>	05-07-2011
41	M/s. Reevax Pharma Limited, 502 Rohini Apt. Srinagar Colony Road, Hyderabad-500073 AP	1. XOIN (A topical tissue adhesive)		<u>Regulated</u>	18-07-2011

42	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)		<u>Not Regulated</u>	09-08-2011
43	M/s. Nipro India Corporation Pvt. Ltd., 503/504 Sai Capital, Opp. ICC Tech Park, Senapati Bapat Road, Pune 411016	1. Dialyzer		<u>Not Regulated</u>	24-08-2011
44	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 manufacturing licesne		<u>Regulated</u>	06-09-2011
45	M/s. G.S.T. Corporation, B-13, Okhla Industiral Area, Phase II, New Delhi-20	1. Reusable Veterinary Needles		<u>Regulated</u>	20-09-2011
46	M/s. Fresinius Kabi India Pvt. Ltd., Echelon Institutional Area, Plot No. II, Sector-32, Gurgaon-122001	1. Feeding Tubes: Freka Tube		<u>Not Regulated</u>	20-09-2011
47	M/s. Ypsomed India Pvt. Ltd., 10/61/1 F, Kirti Nagar, Industiral Area, New Delhi-110015	1. Lancet Needles		<u>Not Regulated</u>	20-09-2011
48	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, Near Picket, Secunderabad-500009 (A.P)	1. Ulthera System		<u>Not Regulated</u>	21-09-2011

49	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, Near Picket, Secunderabad-500009 (A.P)	1. Viberec™ Penile Vibratory Stimulation device		<u>Not Regulated</u>	21-09-2011
50	M/s. Becton Dickinson India Pvt. Ltd., 5th & 6th Floor, Signature Tower-B, South City-I, Gurgaon-122001	M/s. BD Oralpak™ Oral Dosing Dispenser		<u>Not Regulated</u>	21-09-2011
51	M/s. 12iHealth Trading Pvt. Ltd., 413/414 Oxford Tower, 139 Old Airport Road, Kodihalli (Opp. Leela Place), Bangalore-560008	1. LungFlute		<u>Not Regulated</u>	27-09-2011
52	M/s. Swedish Trade Council C/o Embassy of Sweden, New Delhi	1. Digital Cardio Rhythm Analyzer-Dinamika		<u>Not Regulated</u>	30-09-2011
53	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)		<u>Regulated</u>	30-09-2011
54	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		<u>Not Regulated</u>	30-09-2011

55	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		<u>Not Regulated</u>	30-09-2011
56	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>	18-10-2011
57	M/s. GST Corporation, B-13, Okhla Industrial Area, Phase-II, New Delhi-110020	1. Latex Male Catheter/Connector		<u>Regulated</u>	25-10-2011
58	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>	25-10-2011
59	M/s. Nirmal Biotech, E/2, Manjaplur, Township No. 1, Opp. Sandalwood, Soc. Manjalpur, Vadodara-390011, Gujarat	1. Silicone Oil and Intraocular Gases		<u>Regulated</u>	25-10-2011
60	M/s. Allergan India Private Limited, Lvel-2, Prestige Obelisk No. 3, Kasturba Road, Bengaluru-560001	1. Eyegiene		<u>Not Regulated</u>	25-10-2011

61	M/s. LIV Medica, 2-395, Mookamblga Nagar, Kattupakkam, Chennai-600056	1. First Aid Kits for exports		<u>Regulated</u>	11-11-2011
62	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	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	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>	21-11-2011
65	M/s. LIV Medica, 2-395, Mookamblga Nagar, Kattupakkam, Chennai-600056	1. Adhesive Bandages		<u>Regulated</u>	21-11-2011
66	M/s. Virdis 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>	21-11-2011
67	M/s. Smith & Nephew Healthcare Pvt. Ltd., 203 B, Dynasty Business Park, Andheri Kurla Road, Andheri (East), Mumbai-400059	1. IV 3000 and OpSite Flexifix		<u>Not Regulated</u>	21-11-2011

68		2. Opsite Incite and Opsite Post-op		<u>Regulated</u>	
69	M/s. Bhabha Atomic Research Centre Hospital Anushaktinagar, Mumbai-400094	1. Used for Manula removal of stool/faeces		<u>Not Regulated</u>	22-11-2011
70	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)		<u>Not Regulated</u>	22-11-2011
71	Sh. Narendra Vashista, Foreign Trade Development Officer, Ministry of Commerce & Industry, Government of India, DGFT, Udyog Bhavan, New Delhi	1. Othopaedic Implants		<u>Regulated</u>	24-11-2011
72	M/s. Smith & Nephew Healthcare Pvt. Ltd., 203 B, Dynasty Business Park, Andheri Kurla Road, Andheri (East), Mumbai-400059	1. PICO Pump		<u>Not Regulated</u>	07-12-2011
		2. Dressing and Stirips		<u>Regulated</u>	
73	Mr. B.S. Kain, (Section Officer) Nirman Bhavan, New Delhi	1. Latex Male Connector		<u>Not Regulated</u>	09-12-2011
74	Mr. B.S. Kain, (Section Officer) Nirman Bhavan, New Delhi	1. Re-Usable, Non-Sterile Needle for suture		<u>Not Regulated</u>	09-12-2011

75	The ADC(I), CDSCO Sub Zonal Ahmedabad, Aire Cargo Complex Old Terminal Building, Airport Ahmedabad-380016	1. Dental Implants		<u>Regulated</u>	09-12-2011
76	M/s. G.S.T. Corporation, B-13, Okhla Industiral Area, Phase II, New Delhi-20	1. Re-Usable, Non-Sterile Needle for suture		<u>Not Regulated</u>	09-12-2011
77	M/s. Stericat Gutstrings(P) Ltd., 169, Sector-4, IMT Manesar, Gurgaon, Haryana-122050	1. Sterile Monofilament Polypropylene Mesh		<u>Regulated</u>	09-12-2011
78	M/s. A S Smokefree Electorinc Cigarette Pvt. Ltd., G-4, Southx-2, New Delhi-110048	1. Electronic Cigarette		<u>Not Regulated</u>	09-12-2011
79	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	<u>Not Regulated</u>	09-12-2011
80	M/s. Wellset Ortho, No. 402, Gokul Classic, Above Karur Vysya Bank, Nizampet Road, Hyderabad-500072	1. Fiberglass Casting Tape		<u>Regulated</u>	09-12-2011
		2. Water repellent Underpad		<u>Not Regulated</u>	
81	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	<u>Regulated</u>	09-12-2011

82	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	<u>Regulated</u>	20-12-2011
83	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 cryoperservation of stem cells	<u>Not Regulated</u>	20-12-2011
84	Sh. R. K. Pathni (G.p. Capt) O i/c RC Cell Raksha Mantralaya, Karyalaya Maha Nideshak, Sashastra Sena Chikitsa Sewa, 'M' Block, New Delhi-110001	1. Vacuumised Tubes 2. Disposable Hypodermic Needles		<u>Not Regulated</u> <u>Regulated</u>	20-12-2011
85	M/s. Manish Enterprises, 2/19, Bhuta Nivas, Dr. Ambedlar Road, Matunga, Mumbai-400019	1. I.V. Fixator	Used to holds I.V. Cannula	<u>Not Regulated</u>	23-12-2011

86	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		<u>Not Regulated</u>	30-12-2011
87	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kakguda, Near Picket, Secunderabad-500009 (A.P)	1. VibeX		<u>Regulated</u>	30-12-2011
		2. Avendro Inc.'s KXL Systems's		<u>Not Regulated</u>	