

2014 Database

S. NO.	File . No.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	29/Misc/3/2013-DC(177)	M/s. DHR Holding India Pvt. Ltd., Plot NO. 121, Phase IV, Udyog Vihar, Gurgaon 122002	1. HemoCue Cleaners	Use for cleaning the cover glasses of the optronic Unit for HemoCure photometers and analyzers	Not Regulated	1/3/2014
2	29/Misc/3/2013-DC(163)	M/s. Smith & Nephew Healthcare Pvt. Ltd., B-508, 509, Dynasty Business Park, Andheri-Kurla Road, Andheri (E), Mumbai 400059	1. External Fixation Systems	Taylor Spatial Frame and JET-X Extrenal Fixator, and external method of skeletal Immobilization	Not Regulated	1/15/2014
3	3(M/D)/2013-DC(116)	M/s. Becton Dickinson India Pvt. Ltd., No. 34 Assisi Nagar, West Thottam, Madhavram, Chennai 51	1. BD Vacutainer Blood Transfer Device (without needle)		Not Regulated	1/15/2014
4	29/Misc/3/2013-DC(181)	M/s. Coloplast (India) Pvt. Ltd., Khasra Nos 44/14/2, 17 & 47/4,5,6,7 Village-Taj Nagar, Patudi Road, District-Gurgaon	1. Coloplast Paste & Brava Strip Paste	A periwound dressing intended for filling in cavities/folds in the skin around the stoma and protecting skin against stoma output	Regulated	1/15/2014
5	29/Misc/3/2013-DC(164)	M/s. Coloplast (India) Pvt. Ltd., Khasra Nos 44/14/2, 17 & 47/4,5,6,7 Village-Taj Nagar, Patudi Road, District-Gurgaon	1. Comfeel Cleanser 2. Brava Protective Sheet	1. Intended for cleansing of skin exposed to urine, faeces, urine and pus and in removing skin barriers. 2. Intended for protection of skin against stoma output, and for skin protection.	Regulated	1/15/2014
6	29/Misc/3/2013-DC(187)	M/s. Occu'passion Retails Pvt. Ltd., 1-106, Road No. 3, Himgiri Enclave, Chander Vihar, Nilothi Extension, New Delhi-41	1. EPI-Mini- Mobile ECG Monitoring Device	Which enables individuals to instaneously record their heart rhythm measurement (ECG) at a touch of their fingers with clinical precision providing remote health monitoring solution	Not Regulated	1/15/2014
7	29/Misc/3/2013-DC(189)	M/s. Sken Healthcare Pvt. Ltd., B-1001, Growmore Towers, Plot No. 5, Sector-2, Kharghar, Navi Mumbai, Maharashtra 410210	1. Natalis Birth Gel	Consisting of 1 sterile disposable syringe each containing 15 ml Birth gel individually packed in sterile packaging with vaginal catheter intended for easing vaginal birth	Regulated	1/15/2014
8	29/Misc/3/2013-DC(108)	M/s. Terra India, 5/20, Punjabi Bagh Extn., New Delhi 110026	1. Cold Box 2. Mannual Ventose(Vaccum Extractor) 3. Mask 4. Oxygen Flow Regulator 5. Vaccination Carrier 6. Comkunity Health Worker Kit		Not Regulated	1/15/2014
9	29/Misc/3/2013-DC(172)	M/s. Progen SAA Technologies India (P) Ltd. 809, Eighth Floor, Tower-I Pearls Omaxe, Netaji Subhash Place, Pitampura, New Delhi 110034	1. Disinfectants (Antiseptica Combi Instrument-N & Triacid-N	Use for disinfection of instruments & laboratory equipment	Regulated	1/20/2014
10	29/Misc/3/2013-DC(155)	M/s. Gnana Medical Private Limited, Old No. 16, Defence Colony, Edaduthangal, Chennai-097, Tamil Nadu	1. Gnana Laryngeal Airway	Use for Cardiopulmonary resuscitation and during surgery to allow anesthetic gases and oxygen to enter into a patients lung	Regulated	1/21/2014
11	29/Misc/3/2013-DC(130)	M/s. India Medtronic Pvt. Ltd., 4-16 Mohan Co-operative Industrial Estate Ltd., Ground Floor, Mathura Road, New Delhi-110044	1. Ambulatory Insulin Infusion Pump Reservior 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	Regulated	1/21/2014

12	29/Misc/3/2013-DC(169)	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	Regulated	1/21/2014	
			2. Barrier Surgical Staff Clothing, 3. Barrier Supplementaries (Stand Covers, Table Covers, Pouches, Equipment Drapes) 4. Barrier Easywarm Blanket		Not Regulated		
13	29/Misc/3/2013-DC(147)	M/s. Eucare Pharmaceuticals Private Limited, Plot No. AC-25B, SIDCO Industrial Estate, Thirumudivakkam, Chennai 600044	1. EUCAPS Concentrated Autologous Platelet System	Use for separation platelets from autologous whole blood is available as a kit consisting of Hypodermic syringe coated with ADP, three way stop cock, filters, saline solution etc	Regulated	1/21/2014	
14	29/Misc/3/2014-DC(05)	M/s. Group Pharmaceuticals Ltd., Devraj Bldg, A Wing 4th Floor, S.V. Road, Goregan, Mumbai 400062	1. BioFilm, Mouth Ulcer Dissolvable Strips	BioFilm, a mouth Ulcer Dissolvable Strip intended for topical application to areas of the mucosal surface affected by minor aphthous ulcers, oral abrasions or cuts	Regulated	1/28/2014	
15	29/Misc/3/2014-DC(06)	M/s. Pushpanjali Medi India Pvt. Ltd., Gandhi House, 16, Ganesh Chandra Avenue, 5th Floor, Kolkata 700013	1. Glustitch-Twist Topical Tissue Adhesive	Use the topical closure of surgical skin incisions and trauma induced laceration in areas of low skin tension uncomplicated skin lacerations where there is little or no tissue loss.	Regulated	1/28/2014	
16	29/Misc/3/2014-DC(04)	M/s. Sharma Dental Supply Co. Newal Kishore Road, Hazratganj, Lucknow 226001	1. CollaPlug-C, Hemostatic Collagen Sponge	Use as Hemostatic Agent	Regulated	1/28/2014	
17	29/Misc/3/2014-DC(09)	M/s. ISCON Surgicals Ltd., B-70, Marundhar Industrial Area, Phase-II, Bansi, Jodhpur, Rajasthan-342005	1. Bone Marrow Biospy Needle-Unsterile Bulk		Regulated	2/25/2014	
18	29/Misc/3/2013-DC(151)	M/s. Viridis BioPharma Pvt. Ltd., 6/10 Jogani Industrial Complex, V.N. Purav Marg, Chunabhatti, Mumbai 400022	1. Dental Sealant		Regulated	2/25/2014	
19	29/Misc/3/2014-DC(12)	M/s. Surgimedik Healthcare, 1B-904, Green Acres, Lokhandwala Complex, Andher (W), Mumbai-400053	1. Dexell	Use for Vesicoureteral Reflux (VUR)	Regulated	3/7/2014	
20	29/Misc/3/2014-DC(24)	M/s. Deputy Drugs Controller (I), CDSCO (South Zone) 2nd Floor, Shastri Bhawan Annexe 26, Haddow Road, Chennai-06	1. Negative Pressure Wound Therapy Machine		Not Regulated	4/23/2014	
21	29/Misc/3/2014-DC(21)	M/s. Clairvoyance Consulting, Flat No. 801, 8th Floor, Indra Prakash Building, 21 Barakhamba Road, New Delhi-110001	1. TorqMax	Use in providing grip on outer support sheaths, dilator sheaths and spectranetics laser sheaths	Not Regulated	4/30/2014	
22	29/Misc/3/2014-DC(23)	M/s. Surgimedik Healthcare India Pvt. Ltd., Surgimedik House, 53 CD, Kandivali Co-operative Industrial Estate, Charkop, Kankivali West, Mumbai-40067	1. Guidewires		Regulated	4/30/2014	
23	29/Misc/3/2014-DC(10)	M/s. Wellness Concepts, 10, Om Appartments, Sundervan Complex, Near Sab TV, Andheri (W), Mumbai-400053	1. FitNes	Use as an adjunctive therapy for reducing the frequency of seizure in patients who are refractory to antiepileptic medications	Not Regulated	4/30/2014	
24	29/Misc/3/2014-DC(07)	M/s. Genesee Criticare Device Pvt. Ltd., 303, Aggarwal Complex, Block A-1, LSC, Janakpuri, New Delhi-110058	1. The Tandem Heart System	Use for the temporary circulatory support as Ventricular Assist device by optimal unloading of ventricle to recover from cardiogenic shock	Regulated	5/2/2014	
25	29/Misc/3/2013-DC(28)	Dr. V. Bhujanga Rao, 29, DRDO Bhawan, Rajaji Marg, New Delhi-110011	1. Cochlear Implant	By this directorate under the category of Internal Prosthetic Replacement	Regulated	5/5/2014	

26	29/Misc/3/2014-DC(31)	M/s. Nanz Med Scinces Pharma (P)Ltd., Rampur Ghat, Paonta Sahib, District Sirmour, H.P	1. Isopropyl Alcohol/ Pre Injection Swabs		Regulated	5/6/2014	
27	29/Misc/3/2014-DC(19)	M/s. Terumo Penpol Ltd., Deviprabha, T.C 9/1330(15) Kattachal Bhagavathy Lane, Sasthamangalam, Thiruvananthapuram-695010	1. Mirasol Platelet Disposabale Kits for Tretment in Plasma 2. Mirasol DOUBLE + Platelet Disposable Kit for Treatment in plasma 3. Mirasol Platelet Disposable Kit for treatment in Platement Additive Solution 4.Mirasol DOUBLE + Platelet Disposable Kit for treatment in Platelet Additive Solution	Use for the treatment in plasma/ platelet additive solution	Regulated	5/6/2014	
28	29/Misc/3/2013-DC(179)	M/s. India Medtronic Pvt. Ltd., 4-16 Mohan Co-operative Industrial Estate Ltd., Ground Floor, Mathura Road, New Delhi-110044	1. Deep Brain Stimulation Kit, Spinal Cord Stimulation Kit, Intersim Test Stimulation Kit	Intended to deliver electrical stimulation to selected areas of the brain, spinal cord or peripheral nervous systems	Not Regulated	5/15/2014	
29	29/Misc/3/2013-DC(26)	Prof. N. Khandelwal President, Indian Society of Vascular & Interventional Radiology Department of Neuroradiology, CN Centre, Room No. 15, AIIMS, Ansari Nagar, New Delhi-110029	1. Polyvinyl Alcohol Foam (PVA)		Regulated	5/21/2014	
30	29/Misc/3/2014-DC(39)	M/s. Abbott Healthcare Pvt. Ltd., Corporate Park Sion Trpmbay Road, Mumbai-400071	1. OROSOL spray	Intended as an adjuant in the management of chemo & radio therpy including oral mucositis or ulcer of the oral mucosa alongwith standard treatment	Regulated	5/30/2014	
31	29/Misc/3/2014-DC(34)	M/s. Surgiplus, Plot No. 2, 5th Cross, Gnanaprakasam Nagar, Pondicherry-605008	1. Scalp Vein Infusion Sets 2. Extension Tube 3. 3 Way stopcock 4. Disposable Syringe		Regulated	6/4/2014	
32	29/Misc/3/2014-DC(22)	M/s. Terumo Penpol Ltd., Deviprabha, T.C 9/1330(15) Kattachal Bhagavathy Lane, Sasthamangalam, Thiruvananthapuram-695010	1. Spectra Optia Exchange set 2. Cobe Spectra Product 3. Trima Accel Product		Regulated	6/4/2014	
33	29/Misc/3/2014-DC(48)	Mr. S S Bhatia Col, Dy. Commandant, Armed Forces Medical Stores Depot, Delhi Cantt-10	1. Ligating Clips		Regulated	6/6/2014	
34	29/Misc/3/2014-DC(42)	M/s. Medilinks Inc., 03, Noble House, Gr. Flr, Dr. Batliawala Labe Parel, Mumbai-400012	1. External Breast Prosthesis Maxima		Not Regulated	6/9/2014	
35	29/Misc/3/2013-DC(190)	M/s. Earthrays Pvt. Ltd., 48 Qutab View Apts., Shaheed Jeet Singh Marg, New Delhi-110016	1. BEMER (Sets, PRO & Classic)	Use to support the body's fundamental physiological process,thereby promoting the improvement of natural self regulatory mechanishm on micorcirculations, immune system, protein synthesis	Not Regulated	6/9/2014	
36	29/Misc/3/2014-DC(17)	M/s. Win Medicare Private Ltd., 1400, Modi Tower, 98 Nehru Place, New Delhi-110019, India	1. Contractubex OIP (Overnight Intensive Patches) Transdermal Patches		Regulated	6/25/2014	
37	29/Misc/3/2014-DC(50)	Mr. Samir Mehta, Bio-Medical Engineer, C-150, Oshiwara Industrial Centre, Opp. Oshiwara Bus Depot, New Link Road, Goregaon (west) Mumbai-400104	1. Esophagel Stent & Biliary Stent		Regulated	7/4/2014	

