

2011 Database

S. NO.	File . No.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	29/Misc/14/2010-DC(2)	M/s. Embrace, 1902 Divisadero Street, San Francisco, CA 94115, USA	1. EIW 2010-002	Using Embrace Infant in Low birth Weight Neonates	Not Regulated	1/13/2011
2	29/Misc/3/2010-DC(82)	M/s. Precision Coatings Pvt. Ltd., 101, Prince's Centre, 6/3, New Palasia, Indore-452001 (M.P)	1. Non-woven fabric adhesive coated rolls		Regulated	1/31/2011
3	29/Misc/3/2010-DC(84)	M/s. Jindal Medical & Scientific Instruments Company (Pvt.) Ltd., C-53A, Mansarovar Garden, New Delhi-110015	1. Sea Tangle Tents (Laminara Tents) a Cervical Dilator		Not Regulated	1/31/2011
4	29/Misc/3/2010-DC(83)	M/s. Medicare Products Inc., C-53 A, Mansarovar Garden, New Delhi-110015	1. Sea Tangle Tents (Laminara Tents) a Cervical Dilator		Not Regulated	1/31/2011
5	29/Misc/3/2010-DC(86)	M/s. Insightra Medical Pvt. Ltd., 1201, Bldg. No. 15, Indradarshan, Phase II, Near Millat Nagar, Andheri (W), Mumbai-400053	1. Hernia repair implants		Regulated	1/31/2011
6	29/Misc/3/2011-DC(01)	The Addl. Drugs Controller, Drugs Control Department, Government of Karnataka, Place Road, Bangalore-01	1. Surgical Mesh for Hernia repai and Non-woven Microporous surgical Tapes		Regulated	1/31/2011
7	29/Misc/14/2010-DC(3)	M/s. Cardiomedics Inc., 7 Whatney, Suite B, Irvine, CA 92618	1. Cardiasist External Counter Pulsation (ECP) System		Not Regulated	2/4/2011
8	29/Misc/3/2011-DC(9)	Sh. Ram Chnder, Under Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Shastri Bhawan, New Delhi	1. Adult Diaper		Not Regulated	2/14/2011
9	4-MD/CT-56/2010-DC	M/s. Max Neeman International Limited, Max House, Ground Floor, 1 Dr. Jha Marg, Okhla Phase III, New Delhi-110020	1. Check-Cap's P1 Capsule System in Patients eligible for CRC screening		Not Regulated	2/18/2011
10	29/Misc/3/2011-DC(04)	M/s. Mitra Industries (P) Ltd., 14/4, Delhi-Mathura Road, Faridabad-121003	1. Esophageal stents, Biliary stents, Colo-rectal Stens, Pyloric/Duodenal stents and Tracheobronchial stent		Regulated	2/18/2011
11	29/Misc/5/2011-DC (Fenwal)	M/s. Fenwal India Pvt. Ltd., Upper Ground Floor, Tower B, DLF Building No. 10, DLF Cyber City, DLF Phase II, Gurgaon-122002, Haryana	1. Thermogenesis AXP AutoXpress System		Not Regulated	2/23/2011
			2. Manual Bag Sets having Processing/Plasma bag with sterile docking input line and clot filter, RBC bag, freezing bag total capacity: 25ml, Cyroprotectant line with sterile filter an intergrated segments for sterile sample collection		Regulated	
12	29/Misc/3/2010-DC(77)	M/s. Nobel Biocare India Pvt. Ltd., "Fortune 2000" 1st Floor, 'C' Wing, Bandra-Kurla Complex Bandara (E) , Mumbai-40001	1. Custom made dental products 2. Dental tools and accessories		Not Regulated	3/7/2011
13	29/Misc/3/2010-DC(93)	M/s. Win International Networks, Block 705, # 03-2569, Ang Mo Kio Avenue 8, Singapore 560705	1. Air purifying 'I SIG' (Air Filter + Mouth Flavourer)		Not Regulated	3/7/2011
14	29/Misc/3/2010-DC(96)	Dr. Sambhav Shah (M.S. Orthopaedic), 404, Simla House, E Block, Nepensea Road, Mumbai-400036	1. Humazone Machine		Not Regulated	3/8/2011
15	29/Misc/3/2011-DC(13)	M/s. Confident Sales India Pvt. Ltd., No. 47, 2nd Floor, Pete Channappa Indl. Estate Kamakshipalya, Magadi Road, Bangalore-560079	1. Synthetic Bone Graft Substitute (Bone Medik)		Regulated	3/10/2011
16	29/Misc/3/2011-DC(14)	M/s. Romsons Juniors India Unit-II, C-1 Foundry Nagar, Agra-282006	1. Non-Sterile bulk needles ready for sterilization and packing		Regulated	3/15/2011
17	29/Misc/3/2010-DC(87)	M/s B Braun Medical (India) Pvt. Ltd., III Floor, 23-A, Shivaji Marg, Najafgarh Road, New Delhi-110015	1. Orthopilot Navigation System		Not Regulated	3/15/2011
18	29/Misc/3/2011-DC(31)	M/s. Truskin Gloves Pvt. LTD., Plot No. 14C, Cochin Special Economic Zone, Kakkanad, Cochin-682037	1. Sterile Surgical Gloves		Not Regulated	4/6/2011
19	29/Misc/3/2011-DC(33)	Swedish Trade Council, C/o Embassy of Sweden, Nyaya Marg, New Delhi-110021	1. BIP Foley Catheter		Regulated	4/6/2011
20	29/Misc/3/2011-DC(32)	M/s. Rihim Pharma Consultancy Pvt. Ltd., 518-519, 5th Floor, Ring Road Mall, Mangalam Place, Sec-3, Rohini, New Delhi-110085	1. Blood Bags		Regulated	4/6/2011

21	29/Misc/3/2011-DC(37)	Sh. Sudhir Kumar, Under Secretary to Government of Inida, Nirman Bhavan, New Delhi	1. KKT Treatment Technology	Not Regulated	4/18/2011
22	29/Misc/3/2011-DC(28)	Mr. I.K. Vijay, Swedish Trade Council, C/o Embassy of Sweden, 4-5 Nyaya Marg, Chanakyapuri, New Delhi 110021	1. Components - Transmitter, inserter and receiver of DexcomTM Seven® PLUS Continuous Glucose Monitoring System 2. Sensor	Not Regulated Regulated	4/18/2011
23	31-731-MD/2009-DC End. 01	M/s. Baxter (India) Private Limited, 2nd Floor, Tower C, Building 8, DLF Cyber City, DLF, Phase II, Gurgaon-122002	1. Xenium LF Dialyzers	Not Regulated	4/18/2011
24	31-731-MD/2009-DC	M/s. Baxter (India) Private Limited, 2nd Floor, Tower C, Building 8, DLF Cyber City, DLF, Phase II, Gurgaon-122002	1. CA-HP Dialyzer	Not Regulated	4/18/2011
25	29/Misc/13/2011-DC(4)	M/s. Boston Scientific International B.V., 100 A, The Capital Court, Old Palme Marg, Munirka, New Delhi-110067	1. OPTI-MIND clinical outcomes of Pacemaker Patients acc. to pacing modality and primary indications.	Not Regulated	4/25/2011
26	29/Misc/13/2011-DC(5)	M/s. Biotronik Medical Devices India Pvt. Ltd., 101-106, Plot No. 14, LSC Kalkaji, New Delhi-110019	1. REMOTE-EVIA Registry for Pacemaker Offering Therapy Enhancement-EVIA	Not Regulated	4/25/2011
27	29/Misc/10/2010-DC (United Poly Eng.)	M/s. Untied Poly Engineering Pvt. Ltd., Okhla Industrial Area, Phase-II, New Delhi-110020	1. Medical Utensils and Hospital Furniture	Not Regulated	4/26/2011
28	29/Misc/5/2011-DC(41)	Dr. N.K. Agarwal Deputy Director Gernal (Ophth), DGHS Nirman Bhawan, New Delhi	1. Contact Lens Cleaning Solution	Not Regulated	5/5/2011
29	29/Misc/3/2011-DC(46)	Allwing Lifecare, 4, Damji Shamji Ind. Complex, Off. M.C. Road, Andheri (East), Mumbai-400093	1. Tranfusion Set 2. Infusion Set 3. Scalp Vein Infusion Set 4. A.V. Fistula Needle 5. Blood Line Tubing	Regulated	5/30/2011
30	29/Misc/5/2011-DC (M/s. Mediglobe System)	M/s. Mediglobe Systems, #2 Swamibathan Street, Ramalingapuram, Chennai-600012	1. Multi Sample Needle 22G 1 2. Multi Sample Needle 21G 1 3. Multi Sample Needle 20G 1.5 4. Multi Sample Needle 22G 3/4	Regulated	6/1/2011
31	29/Misc/3/2011-DC(47)	M/s. Sisco Medical Devices (P) Ltd., 6/153, Mount Poonamallee Road, Chennai 600089	1. Bulk Pack unsterile needles import vide BOE No. 817509	Regulated	6/7/2011
32	29/Misc/14/2011-DC(7)	M/s. Max Neeman International Limited, Max House, Ground Floor, 1 Dr. Jha Marg, Okhla Phase III, New Delhi-110020	1. Digital Ballistocardiogram and Echocardiogram	Not Regulated	6/9/2011
33	29/Misc/3/2011-DC(22)	Mr. Labhesh V. Lunkad, 20/125, Anand Krupa, Civil Hudco, Near Jain Temple, Savedi Road, Ahmednagar, Maharashtra-414003	1. Magnetic Device	Not Regulated	6/9/2011
34	29/Misc/3/2011-DC (52)	Mr. Akash Chauhan, Senior Associate, India Law Officers, D-19, (GF), South Extension-I, New Delhi-49	1. Doc Laser	Not Regulated	6/9/2011
35	29/Misc/3/2011-DC(60)	Sh. RK Pathni, GP Capt, O i/c RC Cell, For DGAFMS Raksha Mantralaya, Karyalya Mahanideshak, Shashastra Sena Chikitsaa Sewa, M Block, New Delhi-110001	1. Filter without blood bag	Not Regulated	6/21/2011
36	29/Misc/3/2011-DC(61)	M/s. Friends Consolidation Ltd., #8-2-293/82/A/281-O, Road # 10B, Gayatri Hills, Jubilee Hills, Hyderabad- 500033	1. Haemostatic Pad	Regulated	6/21/2011
37	29/Misc/3/2011-DC(62)	M/s. G.S.T. Corporation, B-13, Okhla Industiral Area, Phase II, New Delhi-20	1. Veusable Veterinary Needles	Regulated	6/22/2011
38	29/Misc/3/2011-DC(73)	M/s. B. Braun Medical (India) Pvt. Ltd., III Floor, 23-A, Shivaji Marg, Najafgarh Road New Delhi-110015	1. Intravenous Infusion Administraion Sets	Regulated	7/5/2011
39	29/Misc/3/2011-DC(68)	S-Three Sales Intl. Pvt. Ltd., D-9, Jangpura Extension, New Delhi-110014	1. Safest Blood Samplling System	Regulated	7/5/2011
40	29/Misc/3/2011-DC(67)	M/s. PAT Pharma Consultants India Pvt. Ltd., Unit No. 2nd Floor, Vikas Surya Arcade, Plot No. 7, CU Block, Pitampura, Delhi-110088	1. Velumont	Not Regulated	7/5/2011
41	29/Misc/3/2010-DC(17)	M/s. Reevox Pharma Limited, 502 Rohini Apt. Srinagar Colony Road, Hyderabad-500073 AP	1. XOIN (A topical tissue adhesive)	Regulated	7/18/2011
42	29/Misc/14/2011-DC(8)	M/s. Max Neeman International Limited, Max House, Ground Floor, 1 Dr. Jha Marg, Okhla Phase III, New Delhi-110020	1. ALERTS (Angelmed for early recognition and treatment of STEMI)	Not Regulated	8/9/2011

43	29/Misc/3/2011-DC(86)	M/s. Nipro India Corporation Pvt. Ltd., 503/504 Sai Capital, Opp. ICC Tech Park, Senapati Bapat Road, Pune 411016	1. Dialyzer		Not Regulated	8/24/2011
44	29/Misc/3/10-DC(92)	M/s. Precision Coatings Pvt. Ltd., 101, Prince's Centre, 6/3, New Palasia, Indore-452001 (M.P)	1. LV. Dressing by way of inclusion in the existing manufacturing license		Regulated	9/6/2011
45	29/Misc/3/2011-DC(62)	M/s. G.S.T. Corporation, B-13, Okhla Industrial Area, Phase II, New Delhi-20	1. Reusable Veterinary Needles		Regulated	9/20/2011
46	29/Misc/3/10-DC(29)	M/s. Fresinius Kabi India Pvt. Ltd., Echelon Institutional Area, Plot No. II, Sector-32, Gurgaon-122001	1. Feeding Tubes: Freka Tube		Not Regulated	9/20/2011
47	29/Misc/3/2011-DC(97)	M/s. Ypsomed India Pvt. Ltd., 10/61/1 F. Kirti Nagar, Industrial Area, New Delhi-110015	1. Lancet Needles		Not Regulated	9/20/2011
48	29/Misc/3/2011-DC(105)	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kaguda, Near Picket, Secunderabad-500009 (A.P)	1. Ulthera System		Not Regulated	9/21/2011
49	29/Misc/3/2011-DC(104)	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kaguda, Near Picket, Secunderabad-500009 (A.P)	1. Viberec™ Penile Vibratory Stimulation device		Not Regulated	9/21/2011
50	29/Misc/3/2011-DC(54)	M/s. Becton Dickinson India Pvt. Ltd., 5th & 6th Floor, Signature Tower-B, South City-I, Gurgaon-122001	M/s. BD Orapak™ Oral Dosing Dispenser		Not Regulated	9/21/2011
51	29/Misc/3/2011-DC(91)	M/s. 12iHealth Trading Pvt. Ltd., 413/414 Oxford Tower, 139 Old Airport Road, Kodihalli (Opp. Leela Place), Bangalore-560008	1. LungFlute		Not Regulated	9/27/2011
52	29/Misc/3/2011-DC(98)	M/s. Swedish Trade Council C/o Embassy of Sweden, New Delhi	1. Digital Cardio Rhythm Analyzer-Dinamika		Not Regulated	9/30/2011
53	29/Misc/3/2011-DC(78)	M/s. Sagar Fossil Fuel Technologies Private Limited, 257-A, 1st Floor, Hauz Rani Market, Press Enclave Road, New Delhi-110017	1. Orthopaedic Bandages (For External Use)		Regulated	9/30/2011
54	29/Misc/3/2011-DC(94)	Dr. K.M. Cherain's, Froniter Lifeline Hospital (A unit of Frontier Lifeline P. Ltd.) R-30-C, Ambattur Industrial Estate Road, Chennai-600101	1. Organ Chamber		Not Regulated	9/30/2011
55	29/Misc/3/2011-DC(93)	M/s. Allwin Lifecare, 4, Damji Shamji Industrial Com. Off Mahakali Caves Road, Andheri (East), Mumbai-400093, Maharashtra	1. Blood Collection Bags with Anticoagulant CPD A1. 2. Blood Collection Bags with Anticoagulant CPD SAGM. 3. Transfer Pack		Not Regulated	9/30/2011
56	29/Misc/3/2011-DC(112)	M/s. Lotus Surgical Pvt. Ltd., 4, Gitanjali, 1st Floor, Plot No. 116-A, Road No. 24-A, Sion (West), Mumbai-400022	1. Skin Staplers		Regulated	10/18/2011
57	29/Misc/3/2011-DC(120)	M/s. GST Corporation, B-13, Okhla Industrial Area, Phase-II, New Delhi-110020	1. Latex Male Catheter/Connector		Regulated	10/25/2011
58	29/Misc/3/2011-DC(113)	M/s. Combindia Biotech Kits (Pvt) Ltd./ 208, Partik Industrial Estate, Mulund- Goregaon Link Road, Next to Wockhardt Hospital, Mulund (West), Mumbai-400078	1. Evacuated Blood Collection Needles Multi Drawing Needles 22x1		Regulated	10/25/2011
59	29/Misc/3/2011-DC(108)	M/s. Nirmal Biotech, E/2, Manjalpur, Township No. 1, Opp. Sandalwood, Soc. Manjalpur, Vadodara-390011, Gujarat	1. Silicone Oil and Intraocular Gases		Regulated	10/25/2011
60	29/Misc/3/2011-DC(116)	M/s. Allergan India Private Limited, Level-2, Prestige Obelisk No. 3, Kasturba Road, Bengaluru-560001	1. Eyegiene		Not Regulated	10/25/2011
61	29/Misc/3/2011-DC(50)	M/s. LIV Medica, 2-395, Mookambiga Nagar, Kattupakkam, Chennai-600056	1. First Aid Kits for exports		Regulated	11/11/2011
62	29/Misc/3/2011-DC(92)	M/s. Akrya 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	Regulated	11/11/2011
63	29/Misc/3/2011-DC(119)	M/s. Global Trade Resources 212, Ansal Chamber-II, Bhikhaji Cama Place, New Delhi-110024	1. Fever Cooling Patch		Regulated	11/11/2011
64	29/Misc/3/2011-DC(106)	M/s. Emergo India Consulting Private Limited, 8/1, First Floor, Vasavi Colony Kaguda, Near Picket, Secunderabad-500009 (A.P)	1. CellTrans ABT Post-operative Blood Transfusion System		Regulated	11/21/2011
65	29/Misc/3/2011-DC(124)	M/s. LIV Medica, 2-395, Mookambiga Nagar, Kattupakkam, Chennai-600056	1. Adhesive Bandages		Regulated	11/21/2011
66	29/Misc/3/2011-DC(118)	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	Regulated	11/21/2011
67	29/Misc/3/2010-DC(99)	M/s. Smith & Nephew Healthcare Pvt. Ltd., 203 B, Dynasty Business Park, Andheri Kurla Road, Andheri (East), Mumbai-	1. IV 3000 and OpSite Flexifix		Not Regulated	11/21/2011
68			2. Opsite Incite and Opsite Post-op		Regulated	

