

2015 Database					
S. NO.	File . No.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status
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
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
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
4	29/Misc./3/2014-DC (146)	M/s. Vigen Healthy Tech India pvt. Ltd., Plot no. 16-17, Near Brahma Apartment Sector-7, Dwarka, new Delhi - 110075	"TOP 8500-Special"	For body massage	Not Regulated
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
6	29/Misc./3/2014-DC (150)	M/s. Serum Institute of India Ltd., 212/2 Hadaspar, Pune-411028	Stratis Needle Free Injector System	Use auto disable needle free jet injector intended to deliver the fluid volumes either intramuscularly (IM) or Subcutaneously (SC) by means of High velocity fluid jet & " stratis reset station" used to prepare (set) the injector spring for an injection	Not Regulated
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
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
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

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
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
12	29/Misc./3/2014-DC (51)	M/s. Duraant Biologicals Ltd., 1-98/9/12A, 2nd Floor, Jain Enclave, T & A Plaza, madhapur, hyderabad 500081	Perfadex	For flushing, storage and transportation of isolated lungs after removal from the donor in preparation for external transplantation into a recipient	Not Regulated
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
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 suprapariosteal deposits of hyaluronic acid for facial tissue augmentation.	Regulated
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, stechscope, probes, thermometer, telemedcare portable health monitor, etc.		Not Regulated
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
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
18	29/Misc./3/2015-DC (30)	M/s. Mtex India Pvt. Ltd., a-26/4, mohan c0-operative industrial estate, mathura road, new delhi-110044	Synthetic casting Tape	synthetic casting tape ' consist of knitted fiberglass (polyester) fabric impregnated with polyurethane resin when exposed to moisture of water initiate a chemical reacton which cause tape to become rigid.	Regulated
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 for the purpose of collecting and transporting blood samples for testing at clinical laboratories/Centrifugatuon.	Regulated
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

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
22	29/Misc./3/2015-DC (144)	M/s. Meril Life Sciences pvt. Ltd. Survey no. 135/2/A, near g m bilakhia stadium muktanand marg chala vapi - 396191	Merigraft pericardium covered stent graft system.	product for examination, testing and analysis .	Regulated
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 intended to increase the oxygen supply to the cells increasing the immune system strength and increasing protection of the body from viruses, microbes, parasites etc.	Not Regulated
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 mucositis that may be caused by radiation or high dose chemotherapy.	Regulated
25	29/Misc./3/2015-DC (145)	M/s. Meril Life Sciences pvt. Ltd. Survey no. 135/2/A, near g m bilakhia stadium muktanand marg chala vapi - 396191	Chronic Occlusion (CTO) Device	Chronic Occlusion (CTO) Device a single use, disposable, sterile catheter for the purpose of examination, test or analysis only at M/s. Merillife sciences pvt. Ltd.	Regulated
26	29/Misc./3/2015-DC (142)	M/s. Meril Life Sciences pvt. Ltd. Survey no. 135/2/A, near g m bilakhia stadium muktanand marg chala vapi - 396191	Intracoronary Shunt	a sterile, single use disposable shunt composed of two bulbs on the distal ends of a flexible shaft for the purpose of examination, test or analysis only M/s. Meril Life sciences pvt. Ltd., survey 135/2/A, near g m bilakhia stadium, muktanand marg, chala, vapi 396191	Regulated
27	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
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
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 an ultra micron pressure sensor die mounted 30 mm from the radiopaque tip of the guidewire for the purpose of examination, test or 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

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
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
32	29/Misc./3/2015-DC (73)	M/s. Paul Hartmann Medical Pvt. Ltd., B/506, 5th Floor, Titanium Square, Thalje, Ahmedabad - 380059, Gujarat	Hydroclean Plus, Hydrotac, Zetuvit, Zetuvit Plus, Permafoam, Cosmopore IV, Hydrofilm IV, Hydrofilm IV control and Peha-haft LF	these products are wound dressing products used in healing of wound and management	Regulated
33	29/Misc./3/2015-DC (81)	M/s. Merz India Healthcare Pvt. Ltd., Level 3, Office No. 337, Neo Vikram, Above audi show room, New Link Road, Andheri (W), Mumbai -400053	Ulthera System	use as a non-invasive dermatological aesthetic treatment to lift eyebrow, lax submental and neck tissue	Not Regulated
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
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
36	29/Misc./3/2015-DC (82)	M/s. CliniExperts Service Pvt. Ltd., 112, 113, 114, C-58, Shahpuri Tower, Janakpuri, New Delhi - 110058	Zip 8i surgical skin closure device and Zip 16 surgical skin closure device	indicated for non-invasive surgical skin closure	Regulated
37	29/Misc./3/2015-DC (66)	M/s. Becton Dickinson India Pvt. Ltd., 5th & 6th Floor, Signature Tower-B, South City-1, Gurgaon-122001	BD Uniject™ DP Prefillable Delivery System	is a container closure system for packing and installation of vaccines and potentially oral drugs	Not Regulated
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
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
40	29/Misc./3/2015-DC (72)	M/s. Observe Design Pvt. Ltd., Level-3, C-28, Malviya Nagar, New Delhi-110017	Sakshield- Hand Sanitizer Dispenser	Hand sanitizer Dispenser (without any disinfectant or sanitizer) which dispenses hand sanitizer using a mechanical or an electronic mechanism	Not Regulated
41	29/Misc./3/2015-DC (75)	M/s. KOB Medical Textiles Pvt. Ltd., No. 116, Trichy Road, Ondipudur, Coimbatore -641016, Tamilnadu	Novopress LF-T 752 and Rinkilastic Cohesive 184 LF	products are latex free elastic, non-woven, hydrophobic cohesive elastic bandage	Regulated
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
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
44	29/Misc./3/2015-DC (71)	M/s. Chandra Corporation, 102, Konark Opp. Sadhanagar, nr. Chepi Rog Hospital, Vedmandir road, karelbau, vadodara -390018	Orthopaedic Casting Tape	used to keep a broken bone in place while it heals	Regulated

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
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, veins 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
47	29/Misc./3/2015-DC (96)	Dr. V.G. Mohan Prasad, VGM Hospital, 2100, Trichy Road, Coimbatore-641005, Tamilnadu	Endoscopic Tubes / pipes	basic endoscopic device (flexible endoscope with 3 internal lumens and around 130cm. Long tube).	Regulated
48	29/Misc./3/2015-DC (100)	M/s. Shree Paetronix Ltd., Plot No. 15, Sector II, Pithampur, dist. Dhar, Madhya Pradesh-454775	Cardiac Pacemaker		Not Regulated
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
50	29/Misc./3/2015-DC (118)	M/s. Johnson & Johnson Pvt. Ltd., 9/43, Kirti Nagar, New Delhi - 110015	Sterile Lancet	used to prick the skin for blood sampling	Not Regulated
51	29/Misc./3/2015-DC (104)	M/s. Emcure Pharmaceuticals Limited, T-184, M.I.D.C. Bhosari, Pune-411026	Histidine-Typtophan-Ketoglutarate (HTK) Solutions	intended for flushing, storage and transportation of isolated lungs after removal from the donor in preparation for external transplantation into a recipient	Not Regulated
52	29/Misc./3/2015-DC (119)	M/s. Ortho Prime, 470, Jawahar Marg Siyaganj, Indore-452007	Fiberglass Orthopedic Tape	used as a casting tape in case of treatment of fractures	Regulated
53	29/Misc./3/2015-DC (80)	M/s. Sceptre 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
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
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
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
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
58	29/Misc./3/2015-DC (127)	M/s. Gel Craft Healthcare (P) Ltd., 306, Deepshikha Building, 43 veer savarkar Block, shakarapur, vikas marg, delhi-110092	C:1 Gel™ Technology based products		Not Regulated
59	29/Misc./3/2015-DC (02)	M/s. Galderma India Pvt. Ltd., Lotus Corporate Park, D Wing Unit 801 & 802, Graham Firth Steel Compound, Western Express Highways, Goregaon Tal: Goregaon (East), Mumbai	Pix'L® and Pix'L® + cannulas	there is no provision for import of device/drug for demo purpose	
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 (TiO2) 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

61	29/Misc./3/2015-DC (143)	M/s. Lakshmi Life Sciences Ltd., 3/284 A, Sular Railway Feeder Road, Kurumbapalayam, M.G. pudur (PO), Coimbatore-641406	1. closed suction catheter (sterile) - catheter 2. 3 way stop cock with extension (Sterile) - Disposable Perfusion Set 3. Yankur suction Set (Sterile) - catheter		Regulated
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
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
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
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 amblyopia and for campimetry	Not Regulated
66	29/Misc./3/2015-DC (153)	m/s. Creative Responsible Integrated System Foundaton, Ground Floor, Madhav Baug, Brahmin Society, naupada, Thane-400602, Maharashtra	G-1 Negative Pressure Ventilator (Portable Ventilator)		Not Regulated
67	29/Misc./3/2015-DC (158)	M/s. Meril Endo Surgery Pvt ltd., Survey No. 135/2/B and 174/2, Third Floor, E1-E3, Meril park, muktanand Marg, Chala, vapi, Dist. Valsad-396191	Ligating Clips	use in surgery for vessel closer as well as for making purposes	Regulated
68	29/Misc./3/2015-DC (158)	M/s. Healthy Options Pvt. Ltd., 14, Vigyan Vihar, Delhi-110092	Electric Massaging Equipment		Not Regulated
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
70	29/Misc./3/2015-DC (150)	M/s. Wealth Taxi Technology Pvt. Ltd., 24/4818, First Floor, Prahlad Street, Ansari Road, Daryaganj, new Delhi-110002	iRemeber (A Smart Pill Organizer)		Not Regulated
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
72	29/Misc./3/2015-DC (79)	M/s. CareFusion, 22745 Savi Ranch Parkway, Yorba Linda CA 92887-4668, USA	AVEA Ventilator care products	1. AVEA Ventilator Esophageal Pressure Monitoring tube set 2. AVEA Ventilator Extension Esophageal Pressure Monitoring tube set (Adult & Pediatric) 3. AVEA Ventilator Nasogastric pressure monitoring tube set (Adult & Pediatric) 4. AVEA Ventilator varflex/ adapter tracheal pressure monitoring tube set	Regulated
73	29/Misc./3/2015-DC (160)	M/s. Schulke India Pvt. Ltd., A-24/9, Mohan Co-operative Industrial Estate, Mathura Road, New Delhi-110044	Thrmosept Xtra	which is a mildly alkaline machine detergent based on surfactants and enzymes for the universal cleaning of medical instruments and accessories is not notified as medical device	Not Regulated
74	29/Misc./3/2015-DC (68)	M/s. Krupa Medix, 3/37, thirumangal Alwar Street, NH-1, Maraimalai Nagar, tamil nadu pin- 603209 M/s. Corions India Pvt. Ltd., No5, Sri Krishna Nagar Annexe, maaduravoyal, chennai-600095	Orthopaedics External Fixation Products	used in infected non-unions of fractures which need correction and for the bone deformities and bone lengthening procedures	Not Regulated
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
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
77	29/Misc./3/2015-DC (163)	M/s. Albert David Limited, 4/11, asaf ali road, new delhi-110002	Both Sterile and Non-sterile Disposable Hypodermic Syringes and Disposable Hypodermic Needled		Regulated
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

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
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
81	29/Misc./3/2015-DC (177)	M/s. Aramex trading Co., 9-ashok Nagar, Lucknow, Uttar Pradesh	Fluor Gel	indicated for the prevention (Prophylaxis) of caries	Regulated
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
83	29/Misc./3/2015-DC (174)	M/s. LifeCell International Pvt. Ltd., #26, Vandalur Kelambakkam Main Road, Keelakkottaiyur, Chennai-600127	Cord collection clamp	used ot collect the umbilical cord blood from umbilical cord during placental delivery of the baby	Not Regulated
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
85	29/Misc./3/2015-DC(181)	M/s. Joseph Lesile & Co. LLP, Leslico House, 3rd Floor, Pro. V. s. Agashe Rd., Dadar-West, Mumbai-400028	Water Gel Based Blankets	used as a body wrap to extinguish fires and to cool and moisten burns	Not Regulated
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
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
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 or subcutaneous injection 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
89	29/Misc./3/2015-DC(09)	M/s. Timpac Healthcare Pvt. Ltd., -169, Naraina Industrial Area, Phase-1, New Delhi-110028	Density Platelet Gel	indicated to be used as a rasp device for femoral broaching	Not Regulated
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
91	29/Misc./3/2015-DC(204)	M/s. UE Marketing Pvt. Ltd., A-102, Universal Paradise, Nanda Patkar Road, Vile Parle (East), Mumbai-400057	iBrest Exam	which is a Breast lesion documentation system	Not Regulated
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
93	29/Misc./3/2015-DC(158)	M/s. Meril Endo Surgery Pvt Ltd., Survey No. 135/2/B and 174/2, Third Floor, E1-E3, Meril park, muktanand Marg, Chala, vapi, Dist. Valsad-396191	Ligating Clips	used in surgery for vessel closer etc., are regulated as drugs under the category of surgical Ligatures (Schedule C)	Regulated
94	29/CDSO/Govt./11/2 015-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
95	29/Misc./3/2015-DC(142)	M/s. Meril Life Sciences pvt. Ltd. Survey no. 135/2/A, near g m bilakhia stadium muktanand marg chala vapi - 396191	Intra coronary Shunt		Regulated
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 catridges for use in the home environment to aid and support prescribed treatment and therapy	Not Regulated

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
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
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
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
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
102	29/Misc./3/2015-DC(217)	M/s. Dr. Schumacher India Pvt. Ltd., 2A, 2nd Floor, 164, M.G.Road, Pune-411001	Cleanisept Wipes Maxi	having bactericidal, fujigicidal and virus inactivating properites which is used for thje rapid disinfection and cleaning of alcohol-sensitive medical devices, medical quipment as well as of other alcohol-sensitive surfaces	Regulated
103	29/Misc./3/2015-DC(219)	M/s. Utanco India, 13, tarun enclave, near pushpanjali, pitam pura, delhi-110034	Orthopaedic casting tapes & splint	intended for use in the construction of orthopaedic casts, temporary immobilization of fractures, sprains and strains	Regulated
104	29/Misc./3/2015-DC(228)	M/s. Sceptre Chemicals Inc., House no. 8-A, 2nd Floor, Siri Nagar Colony, Near Shiva Mandir, Delhi-110052	Citric Acid Solution (Disinfectant)	used for disinfection of hemodialysis machine	Regulated
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
106	29/Misc./3/2014-DC(125)	M/s. Delhi Eye Zone Pvt. Ltd., D-114, (G.F.), lajpat nagar-I, New Delhi-110024	Ferrara Ring- an intraconeaal Implants	used for correction of pathological tissue deformities of the fornea	Regulated
107	29/Misc./3/2014-DC(125)	M/s. Care Group India, A unit of polymer technologies INTL, Block no. 310, village sim of dabhasa, Ta Padra, Dist. Vadodara-391440	coneaal inlay	used for improving the depth of focus by cutting the unnecessary light entering in the eye	Regulated
108	29/Misc./3/2014-DC(125)	M/s. Emergo (india) Consulting Pvt. Ltd., 8/1, First Floor, Vasavi Colony, Kakaguda, Near Picket, Secunderabad, MCH-Circle-7, mandal, Hyderabad - 500009 A.P.	Presbia Flexivue Microlens	indicated to improve near vision in adult presbyopic subjects	Regulated
109	29/Misc./3/2015-DC(221)	M/s.Chemours India Pvt. Ltd., 6th floor, Tower-C, DLF cyber greens, sector-25A, DLF city phase -III, gurgaon-122002, haryana	Relyon perasafe-medical device sterilant	used for sterilization on non-surgically invasive medical devices such as gastroscope 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
110	29/Misc./3/2015-DC(223)	M/s. Johnson & Johnson Pvt. Ltd., LBS Marg, Mulund (West), Mumbai-400080	Temporary Cardiac Pacing Wire	intended for use in temporary cardiac pacing or monitoring	Not Regulated
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

112	29/Misc./3/2015-DC(237)	M/s. Innogen Life Sciences Pvt. Ltd., K-384, Surajpur Site V, Kasna Industrial area, greater Noida -201308	1. adhesive Non-woven rolls 2. Absorbent pad rolls I.V. dressing (sterile) I.V. dressing (Non sterile) 5. self-adhesive surgical wound dressing (sterile) 6. foam dressings (sterile)	1. Raw material for post operative surgical wound dressings 2. Raw material for post-operative surgical wound dressings 3. a. Fixation of I.V.Cannula b. these are suited for post-operative use. They are useful in accident & emergency for cuts, lacerations and sutured wounds. c. fast, efficient & aseptic protection of the puncture points: parenteral feeding, 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
113	29/Misc./3/2015-DC(120)	M/s. Paseca Healthcare LLP., Factory: K-68, Sector-3, Bawana Industrial Area, new Delhi - 110039	Surgical dressings made up of Oxidized Regenerated Cellulose and Oxidized Cellulose		Regulated
114	29/Misc./3/2015-DC(236)	M/s. Dentsply India Pvt. Ltd., Kh. No. 66/20 & 66/11/2, Gali No. 2, Main Rohtak Road, Mundka Industrial Area, New Delhi-110041	Dental filling materials, cementing material, impression materials	used in dentistry	Not Regulated
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
116	29/Misc./3/2015-DC(239)	M/s. Paseca Healthcare LLP., Factory: K-68, Sector-3, Bawana Industrial Area, new Delhi - 110039	1. Hydrocolloid Dressing with Foam 2. Dressing Wound 3. Transparent wound medicated 4. polymen dressing 5. pressing post op medicated		Regulated
117	29/Misc./3/2015-DC(232)	M/s. Ujjawal Overseas (India) Pvt. Ltd., Part-A, Basement, Plot No. 1 & 2, Block B, Kh. No. 15/7/5/2 & 15/7/8, Raghu Nagar, New Delhi - 110045	Blood Collection Needles	used to collect blood for testing	Regulated
118	29/Misc./3/2015-DC(217)	M/s. Dr. Schumacher India Pvt. Ltd., 2A, 2nd Floor, 164, M.G.Road, Pune-411001	Cleanisept Wipes Maxi	having bactericidal, fungicidal and virus inactivating properties which is used for the rapid disinfection and cleaning of alcohol-sensitive medical devices, medical equipment as well as of other alcohol-sensitive surfaces	Regulated
119	29/Misc./3/2015-DC(261)	M/s. Helyxon Healthcare Solutions (P) Ltd., IIT Madras Research Park, No.01, Kanagam Road, Taramani, Chennai-600113	98.6 Fever-watch	used to facilitate monitoring and tracking of the infants or babies temperature	Not Regulated
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
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 indicated for maintenance of immobilization of extremities and for supporting soft and hard tissues e.g. in orthopaedic treatments 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	Regulated
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		Not Regulated

123
124
125
126
127
128
129
130
131
132
133
134
135
136
137

138
139
140
141
142
143
144
145
146
147
148
149
150
151
152
153
154
155
156
157
158
159
160
161
162
163
164
165
166
167
168
169
170
171
172
173
174
175
176
177
178
179
180
181
182
183
184
185
186
187
188
189
190
191
192
193
194
195
196
197
198
199
200
201
202
203
204
205
206
207
208
209
210
211
212
213
214
215

29/Misc./3/2015-DC (138)

M/s. Becton Dickinson India Pvt. Ltd., 5th & 6th Floor, Signature Tower-B, South City-1, Gurgaon-122001

Prefillable Injecton System (BD Uniject™ Prefillable Injection system)

29/Misc./3/2015-DC (164)

M/s. Vashnavi Dental Depot, Khan's Galaxy, Shop No.3, Opp. Sardar Patel Dental College, Rai Bareilli Road, Utrathia , Lucknow U.P.25

216
217
218
219
220
221
222
223
224
225
226
227
228
229
230
231
232
233
234
235
236
237
238
239
240
241
242
243
244
245
246
247
248
249
250
251
252
253
254
255
256
257
258
259
260
261
262
263
264
265
266
267
268
269
270
271
272
273
274
275
276
277
278
279
280
281
282
283
284
285
286
287
288
289
290
291
292
293
294
295
296

297
298
299
300
301
302
303
304
305

Date of Issue
01.01.2015
01.01.2015
01.01.2015
05.01.2015
15.01.2015
19.01.2015
21.01.2015
28.01.2015
30.01.2015

03.02.2015
05.02.2015
05.02.2015
11.02.2015
11.02.2015
11.02.2015
19.02.2015
09.03.2015
09.03.2015
10.03.2015
10.03.2015

10.03.2015
26.03.2015
26.03.2015
27.03.2015
27.03.2015
27.03.2015
27.03.2015
27.03.2015
30.03.2015
01.04.2015

07.05.2015
12.05.2015
18.05.2015
18.05.2015
18.05.2015
20.05.2015
22.05.2015
22.05.2015
26.05.2015
02.06.2015
09.06.2015
12.06.2015
16.06.2015
16.06.2015
19.06.2015
16.06.2015

19.06.2015
30.06.2015
30.06.2015
03.07.2015
07.07.2015
07.07.2015
15.07.2015
15.07.2015
17.07.2015
17.07.2015
21.07.2015
24.07.2015
24.07.2015
29.07.2015 12.06.2012
31.07.2015
31.07.2015
03.08.2015
04.08.2015

05.08.2015
04.08.2015
04.08.2015
04.08.2015
12.08.2015
05.05.2015 12.08.2015
25.08.2015
25.08.2015
31.08.2015
31.08.2015
01.09.2015
01.09.2015
03.09.2015
03.09.2015
03.09.2015
10.08.2016
08.09.2015
21.09.2015

21.09.2015
29.09.2015
29.09.2015
29.09.2015
29.09.2015
29.09.2015
06.10.2015
06.10.2015
06.10.2015
13.10.2015
13.10.2015
13.10.2015
13.10.2015
14.10.2015
09.11.2015

09.11.2015
09.11.2015
09.11.2015
20.11.2015
20.11.2015
20.11.2015
17.12.2015
17.12.2015
18.12.2015
21.12.2015
29.12.2015

















