

2018 Database						
S. NO.	File . No.	Name of the Company and Address	Product Name	Intended Use	Regulatory Status	Date of Issue
1	29/Misc/03/2017-DC (338)	M/s Oralla Dental Private Limited	GIC Inomer Cements	For self curing glass inomer based radiopaque filling cement	Not Regulated	01.01.2018
2	29/Misc/03/2017-DC (340)	M/s Delta Biosciences Pvt.Ltd.	Dental Root Canal Disinfection Kit	For purposes of performing root canals and related dental procedures,by a trained professional in general dentistry	Not Regulated	01.01.2018
3	29/Misc/03/2017-DC (328)	M/s Meril Endo Surgery Pvt.Ltd.	Sterile Surgical Sutures	Nil	Regulated	08.01.2018
4	29/Misc/03/2017-DC (341)	M/s CliniExperts Services (P) Ltd	Infusion Pump	For matching tube or syringe to control the flow rate that is infused into patients	Regulated	08.01.2018
5	29/Misc/03/2018-DC (08)	M/s Orbit Life Sciences Pvt.Ltd.	NovApex N31 Apex Locator	Fro apex localization and working length determination during root canal treatment by dentist	Not Notified	08.01.2018
6	29/Misc/03/2018-DC (21)	M/s Pall India Pvt.Ltd.	1.Pall Ultipor 100 Braething system Filter 2.Pall breathing system filter 3.Pall Pharm Assure 25mm	For eliminating filters or breathing filters	Not Notified	12.01.2018
7	29/Misc/03/2018-DC (04)	M/s Impluse Dynamics (USA) Inc.	Optimizer Smart-A cardiac contractility modulation system	For treating patients with symptomatic heart failure due to left ventricular dysfunction by delivering non excitatory cardiac contractility modulation (CCM) electrical signals to right ventricle	Not Regulated	12.01.2018
8	29/Misc/03/2017-DC (344)	M/s Meril Life Sciences Pvt.Ltd.	Eustachian Tube Balloon Dilation System	Nil	Applied product is not yet approved under rule 63	12.01.2018
9	29/Misc/03/2017-DC (346)	M/s Ingress India Healthcare Consultants	Woudn Care dressing Spray	For in all sorts of medical facilities, which need to treat surgical closure, wound trauma, skin inflammation,suppurative skin infection and providing first sid treatment of all sorts of wound happended in	Regulated	15.01.2018
10	29/Misc/03/2018-DC (10)	M/s Reckitt Benckiser India Pvt.Ltd.	K-Y tm Lubricating jelly	For easy insertion of catheters, scoops, rectal thermometers,enemas,docuhes	Not Notified	15.01.2018
11	29/Misc/03/2018-DC (53)	M/s Air-O -Pure	Air Breath, canned breathing air	Used by officer workers,athletes, pregnant and breastfeeding women,children,persons having asthma and chronic illness citizens	Not Notified	15.02.2018
12	29/Misc/03/2018-DC (02)	M/s Bion Atrium Medical Care Pvt.Ltd.	1.KIWI Omnicup 9VAC 6000M 2.KIWI Omnicup with traction Force Indicator	Used for foetal vaccum delivery assistance in conditions of 1) Dystoica 2) uterine inertia 3) maternal exhaustion (ineffective voluntary effort) or 4) maternal or foetal distress	Not Regulated	15.02.2018
13	29/Misc/03/2018-DC (56)	M/s Philips India Limited, Plot No.B-79,MIDC, Phase-II,Chakan Taluka,Khad, Village Savardan Pune.	Interventional and diganostic X Ray equipment	Nil	Not Notified	15.02.2018
14	29/Misc/03/2017-DC (294)	M/s Conect Critical Solution Pvt.Ltd., A 403-404,Sector-47,Sohna Expressway Gurgaon-	Conectct Sterile Hydropure	Use for sporocidal solution for cleaning/disinfecting hard surfaces coming in contact with the product	Regulated	23.02.2018
15	29/Misc/03/2018-DC (13)	M/s Mylan Pharmaceuticals Pvt.Ltd., Plot No.1-A/2,MIDC, Industrial Area Talaja, Panvel Raigad	End Warts Pen and End Warts Bottle	Used for removal of warts on hands, arms and feet	It comes Definition of Drugs Under as per Section 3(b)(i)	23.02.2018

16	29/Misc/03/2018-DC (03)	M/s Magal Health Care Pvt.Ltd., No.34,2nd Floor, 60 Ft.Road, NGEF Layout, RMV Ind	Rythmic evolution infusion pump without intravenous set/catheter/spike set	Used for administration of prescribed liquid medication and solutions to the body	Not Notified	23.02.2018
17	29/Misc/03/2017-DC (184)	M/s Dialec Medical Services Pvt.Ltd., Plot No.311, Survey No:-197,Block GA, 1st Floor, 1st cross, M.S.Nagar	Citra-Lock solution is claimed to be having anti microbial,anti coagulant and anti bio film properties	Used for prevention catheter related bacteremia and clotting	Regulated	26.02.2018
18	29/Misc/03/2018-DC (68)	M/s NA Life Science, No.19,5th street, Banker's Colony, Kumaran Nagar, Vavalur Road, Trichy-	Fever Cooling Patch	Used for fever management,temporary relief oh headache,toothache and muscle pain	Not Notified	27.02.2018
19	29/Misc/03/2018-DC (78)	M/s CURA Healthcare Pvt.Ltd., No.A-32,Phase-1,MEPZ SEZ, Tambaram Kadapperi,chennai-600045,Tami Nadu,India	Electro mechanical equipmet (Accupush)	Nil	Not Regulated	13.03.2018
			Hypodermic syringes, hypodermic		Regulated	
20	29/Misc/03/2018-DC (80)	M/s Freyr Software Services Pvt.Ltd., Level 4,H-08 Building,SEZ Location-Phoenix Infocity Pvt.Ltd. The Deputy Drugs	Polisorb Devioce (Mineral based gastrointestinal detoxifier)	used for the treatment of diarrhea,nuasea, vomiting,fiatus, bellyache,food borne and drug allergic reactions in adults and children	Regulated	13.03.2018
21	29/Misc/03/2018-DC (54)	Controller (I),4th Floor,Zonal FDA Bhawan,GMSD Compound, Bellasis Rd	Vaprox HC Sterilant	Used as an antimicrobial (effectice against viruses, bacteria, yeasts and bacterial sporeS) when used in V PRO low temperature sterilization system	Regulated	16.03.2018
22	29/Misc/03/2018-DC (101)	M/s Uber Diagnostics pvt.Ltd., No.1670,1st Floor, 18th cross, MC Layout,Viiavangar Bangalore	Cardiotrack device (12 Chennel ECG Device)	To conduct Clinical trials /validations	Not Notified	15.03.2018
23	29/Misc/03/2018-DC (25)	M/s Samson Laboratories Pvt.Ltd., SCO 40,Swastik Vihar, MDC, Sector-5,Panchkula-134109	Motion Sickness Patch	Intended to provide relief from vomiting, nausea, anorexia and other symptoms resulted from sickness of cars, ships, airplanes and other means of transport	Regulated as "Drugs" under Section 3(b)(i)	19.03.2018
			Warmer pad/Menstrual Cramp relief patch	Intended for temporary relief of minor menstrual cramp pain and assocaited back aches by way of heat therapy		
			Cooling Gel Patch	Intended for reducing temperature in fever, relief in tiredness ,sleep ,daze,toothache,headache etc.		
24	29/Misc/03/2018-DC (90)	M/s GlaxoSmithKline Consumer Pvt.Ltd., 24-25 Floor, One Horizon Center, Sector-43,dif Phase -5 Golf	Nasal Congestion Device	Used for reliving nasal congestion in infants	Not Notified	23.03.2018
25	29/Misc/03/2018-DC (110)	M/s Quantleap Consulting,107,primrose, Serene counrty,telecom nagar, hyderabad-500032	Diastolic and systolic leg compression device, a non -invasive compression device	Used externally on intact skin (thigh and calf) to enhance blood flow towards proximal parts of the body by increasing tissue pressure in thigh and leg	Not Notified	23.03.2018
26	29/Misc/03/2018-DC (93)	M/s Immito Meditech Pvt.Ltd., 216A, Humayunpur, Safdarjung Enclave, New Delhi-110029	Implantable neurostimulator DBS System	Used to reduce the sypstoms associated with parkinson's disease	Not Notified	23.03.2018
27	29/Misc/03/2017-DC (332)	M/s DSS Imagtech Pvt.Ltd., A-5,Mohan Industrial Estate, Mathura Road, Delhi-110002	eXeM Foam Kit containinga syringe with ExEm Gel, A syringe with ExEm water and a coupling device	Intended for recongition of tubal aptency during the ultrasound procedure	Regulated	27.03.2018
28	29/Misc/03/2017-DC (330)	M/s RPK Pharma Pvt.Ltd., Plot No.IV, APHB Colony, Pedagantyada,Vishakhapat nam, Andhra Pradesh-530044	Memthol Barrier Spray	Used to get relief from swelling, pain and irritation in patients suffering from haemorrhoids	Not Notified as Medical Device under Section 3(b)(iv)	03.04.2018
				As per the therapeutic claim, the product attracts the definition of the Drug	Regulated as "Drugs"	
29	29/Misc/03/2018-DC (107)	m/S Datt Mediproducts Pvt.Ltd., 56,Community Centre, East of Kailash,New Delhi-110065	Velnext foam Dressing Kit	Nil	Regulated	03.04.2018

30	29/Misc/03/2018-DC (65)	M/s BSN Medical Pvt.Ltd., B-10, Lotus Park, Jay Coach Junction, Opp.Raheja Ridge, Jangpore, Hyderabad-500080	Leukomed IV/IV Film, Fixomull Stretch /Transparent and Leuopor	Intended for holding or fixation of surgical dressings, IV Tubes, catheters etc	Not Notified	06.04.2018
31	29/Misc/03/2018-DC (89)	Monarch Enterprises, 6-6-35/2, Kavadiguda, Secudnerabad, Telanaga-500080 Hyderabad	Eurofix, Eurotrasp and Eurosilik	Intended for fixation of dressings, bandage, tubes, venous catheters and medical probes etc.	Not Regulated	09.04.2018
32	29/Misc/03/2018-DC (119)	M/s AQS Biocair Pvt.Ltd., Rishi Homes, Flat S1, B-Block, No.191, Samyapuram nagar, 6th	Disinfectant solution with active ingredient hypochlorite ions	Intended to disinfect the home, office, healthcare, ambulances, manufacturing unit etc.	Regulated	09.04.2018
33	29/Misc/03/2018-DC (302)	M/s Peroba Ventures Pvt.Ltd., 308, Brigade Gateway Apartements, Dr. Rajkumar Road, M/s Predible Health	Sonata Sonograpghy Guided Transcervical Fibroid Ablation system	Intended for providing radiofrequency ablation of uterine fibroids using a transcervical approach without incisions or material uterine distension	Regulated as ABLATION DEVICE	09.04.2018
34	29/Misc/03/2018-DC (145)	Pvt.Ltd., BN189, Bapuji Nmagar, Pongumoodu, Trivandrum-695011 Kerala	Predible Liver Software Tool	Intended for 3D Visualization, segmentation and quantitative analysis of liver anatomy	Not Notified	10.04.2018
35	29/Misc/03/2018-DC (77)	M/s CURA Healthcare Pvt.Ltd., No.A-32, Phase-1, MEPZ SEZ, Tambaram Kadapperi, Chennai-600045, Tami Nadu, India	SinoPower -S, SinoPower-D and SinoAngio 1200	Used to inject contrast medium for CT and DSA respectively	Not Regulated	12.04.2018
36			Syringe, connecting tube and fill tube	Used to inject contrast medium for CT and DSA respectively	Regulated	
37	29/Misc/03/2018-DC (154)	M/s Medicom International Eyetech Pvt.Ltd., 305-C, Iris Tech Park, Sohna Road, Sector-48, Guram-	ICP Ocular Surface Analyzer	Intended to be used for non invasive full assessment of the ocular surface through a combination of tests for dry eye diagnosis, from tear break up time to the tear volume production test	Not Notified	18.04.2018
38	29/Misc/03/2018-DC (137)	M/s Mylan Laboratories Limited, Plot No.564/A/22, Road No.92, Jubilee Hills, Hyderabad-500034	EndWartz Freeze Naloc Pro, an effective solution	Intended for effective removal of warts from hands, arms and feet by freezing the wart at temperature of -80 degree celcius achieved by pressure mechanism of nitrous oxide (cold gas) Intended for prevention and treatment of nail fungal infection i.e. onychomycosis	Regulated as ABLATION DEVICE Regulated as "Drugs"	19.04.2018
39	29/Misc/03/2018-DC (164)	M/s Intutive Surgical India Pvt.Ltd., C/o Regus Suburb Centres Pvt.Limited, Level 4, Dynasty, A Wing, Andheri	Instrument Arm Drape, Camera Arm and Head Drape, Column Drape and Arm 4 Extension Drape	Intended to maintain sterility of the sterile field when non sterile portions of the da vinci Xi System (IS4000 Surgical System) enter the sterile field by covering the parts of instruments	Not Regulated	23.04.2018
40	29/Misc/03/2018-DC (155)	M/s HP India Sales Pvt.Ltd., Building No.2, DLF Cyber Greens, DLF Cyber City, 1-4 Floor, Tower D & E Phase-	HP Healthcare Edition HC270cr Clinical review Monitor	Intended to view medical images for image capture verification	Not Notified	23.04.2018
41	29/Misc/03/2018-DC (153)	M/s Conva Tech India Pvt.Ltd., SY No.217, Next Logistics Dock -4, Soukya Road, Next to Police	SurePress High Compression Bandage	Intended for use over a primary wound dressing	Not Regulated	23.04.2018
42	29/Misc/03/2018-DC (172)	M/s Divya Baby and Mother care (P) Ltd., 135 F, 2nd Floor, Pocket-IV, Mayure Vihar Phase-1, Delhi-	Divya Double electric breast pump	Intended to be used to smoothen the flow of milk from breast	Not Notified	24.04.2018
43	29/Misc/03/2018-DC (64)	M/s Alcon Laboratories (India) Pvt.Ltd., 3rd Floor, Crescent-4, Prestige Shantiniketan Whitefield, Bangalore	CyPass Ultra System	Intended to be used in conjunction with cataract surgery for reduction of intraocular pressure	Regulated	26.04.2018
44	29/Misc/03/2017-DC (296)	M/s Transpact Enterprises Pvt.Ltd., 204, Timmy Arcade, Makwana Road, MarolA nheri East, Mumbai-	Vestibulator	Intended for vestibular, neuro developmental and sensory integration therapy	Not Notified	01.05.2018
45	29/Misc/03/2018-DC (111)	M/s Dorthom Medi Dents Pvt.Ltd., UNRA 25A, NCC Road, Ambalamukku, Peenakada T	GRABIO GLASCERA	Used in dental periodontal, oral and maxillofacial surgical procedures to enhance the bone regeneration in lost or fractured bone areas, procedures to enhance the bone regeneration in lost	Regulated	09.05.2018
			Foreign Body Retrieval Hood	It is used to retrieve sharp foreign objects from GI tract through the scope. It is fixed on the tip of endoscope to protect mucosal tear and to prevent esophagus tear while removing sharp foreign		
			Balloon Inflation Device	To Inflate Balloon		
			EUS Balloon	For the help of balloon examination of structures within or adjacent to the intestinal wall over the EUS scope		

Multi Band Ligator	Used for endoscopic ligation of esophageal varices at or above gastro esophageal junction
Loop Basket	Used for endoscopic retrieval of foreign bodies from GI tract and to retrieve polyp through colonoscope
Polypectomy Snare	Used for endoscopic excision of polyps using single mono polar electrosurgical unit and retrieval of foreign bodies from GI tract
Spring Tip Steel Guide Wire	Used to guide esophageal dilators for dilatation
Neg Guide Wire	Used to gain access through difficult biliary and pancreatic strictures. To facilitate exchange of compatible wire guided accessories to the desired biliary or pancreatic ducts.
Hydra Neg Guide Wire	Used to gain access through difficult biliary and pancreatic strictures. To facilitate exchange of compatible wire guided accessories to the desired biliary or pancreatic ducts.
Nitinol Black Wire	To gain access through difficult biliary and pancreatic strictures. To facilitate exchange of compatible wire guided accessories to the desired biliary or pancreatic ducts.
Hydra Neg Combo Guide Wire	Hydra neg combo guide wire with tip at both end used to gain access endoscopically through the difficult strictures.
Stiff Guide Wire	Used to gain access endoscopically through difficult strictures
Super Stiff Hydra Neg Guide Wire	Used to gain access through difficult biliary and pancreatic structures and to facilitate exchange of compatible wire guided accessories to the desired biliary or pancreatic ducts.
Wire Guided Stone Extraction Balloon	Used for endoscopic extraction of biliary stones
Single Action Stent Introducer System	Used for easier stent placement and endoscopic biliary stent placement to reduce time
Stent Pusher	For endoscopically biliary stent placement
Biliary Dilator	Used to dilate papilla or biliary strictures through the scope.
ERCP Cannula	Used endoscopically to opacify the biliary duct with radio opaque contrast material for fluoroscopic view
Suction Coagulation Probe	Used for suction and coagulation during endoscopic mucosal resection
Esophageal Dilator	Used to dilate esophageal strictures over previously placed wire guided
Cytology Brush	Used to collect cells from upper and lower gastrointestinal tract
Eso Gastric Balloon Deflation Device	To deflate previously placed ESO gastric balloon
Stone Grasper	Used to facilitate manipulation/ removal of stones can also be used for removing stents from urinary tract
Eso Gastric Balloon Retrieval Device	For retrieval of ESO gastric balloon

Stone Basket	Indicated for the manipulation and removal/retrieval of stones from urinary tract
Nephrostomy Basket	Indicated for the manipulation and removal/retrieval from urinary tract
Probe For Nephrostomy Basket	To apply lithotripsy to break stone from urinary tract
Neg Guide Wire	Used to gain access endoscopically urology through the difficult strictures in urinary tract
Hydra Neg Guide Wire	Used to access urologytract for access and exchange of accessories in urinary tract
Nitinol Black Wire	To gain access through difficult urological strictures. To facilitate exchange of compatible wire guided accessories
Hyneg Combo Guide Wire	Used to gain access endoscopically through the difficult strictures.
Stiff Guide Wire	Used to gain access endoscopically through the difficult strictures
Spray Probe	Used to spray dyeing
Cournual Cannulation Set	Used for ovarian cannulation
Clips For Endoclip	Used to mechanically bind blood vessels
Endoclip Applicator	It is a delivery system used to deliver clips for achieving emostatis for:mucosal/submucosal defeats, bleeding ulcers/arteries, surgery sites
Clipping Device	It is used to close two mucosal surfaces without the need for surgery or suturing or used to mechanically bind blood vessels (the device holds the clips)
Sphincterotome	It is used for endoscopic cannulation of biliary ductal system. It is a triple lumen catheter accommodating a guidewire, cutting wire, contrast medical channel
Needle Knife	It is used for precut pallotomy.It has triple lumen design facilitating for cannulation after incision of the pailla without requiring that the catheter be exchanged. Triple lumen accomodates a guidewire.
Double Pin Bipolar electrode	It neded for ENT Surgery usingquantam molecular resonance generator
Laparoscopic Scissors	Designed to cute,dissect,manipultae and /or cauterize various tissues during endoscopic/laprosopic surgical procedures
Single use Bladder Evacuator	Used to intoroduce fluids into body cavities other than blood vaessels,drain fluids from body caivities or avaluate certain physiologic conditions
Dsisposable lap electrode L Hook and Spatula	Used in Laprosopic surgery for cauterizing and manipulation of tissues and veseels
Laparoscopic Graspers	Used to grasp tissue, retrieve foreign bodies, and remove tissues from within the gastrointestinal tract
Laparoscopic Irrigation Suction Set (LISS Assembly and body probe)	Used to introduce fluids into body cavities other than blood vessels, drain fluids from body cavities, or evaluate certain physiologic conditions.
Single use Biopsy Forceps	Used to collect tissue, or foreign body retrieval, from Gastrointestinal tract using an endoscope
Multiple Band Ligator	Used for endoscopic ligation of oesophageal varices and anorectal haemorrhoids
Cholangiography Clamp	Used for diagnostic evaluation of bile ducts during laprosopic cholecystectomy. They are designed to grasp and introduce contrast medium into gallbladder for evaluation of stones, blockage and or

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29/Misc/03/2017-DC
(334)M/s Glowtronics Pvt.Ltd.,
1D, Hootagalli Industrial
Area,Mysore-570018,India

Not Regulated

Regulated

09.05.2018

			Endoscopic Ultrasound (EUS) Needle	Used to sample targeted submucosal gastrointestinal lesions through the accessory channel of an ultrasound endoscope		
			Pleural drain	Used to drain fluids from the chest cavity		
48	29/Misc/03/2018-DC (87)	M/s Confident Sales India Pvt.Ltd., No.47,2nd floor, Pete Channappa Industrial Estate,Magadi Main Road, Kamakshipalya,Bangalore-560079	Clearfill SE Bond	Intended use direct filling restorations using light curing composite or compomer, cavity sealing as pretreatment for indirect restorations, treatment for hypersensitive and/or exposed root surfaces	Not Regulated	11.05.2018
			Panavia F2.0	Intended use cementation of metal crowns and bridges, inlays and onlays, porcelain crowns, veneers, resin crowns, adhesion bridges, endodontic cores and prefabricated post bonding		
			Clearfill AP-X	Intended use direct restorations for anterior and posterior teeth Class III,IV,V restorations of anterior teeth, cervical cavities of root surfaces defects		
			Clearfill AP-X Esthetics	Intended use direct restorations for anterior and posterior teeth (Class I-V Cavities), Direct veneers, correction of tooth position and tooth position and tooth shape (diastema closure)		
			Clearfill AP-X Flow	Intended use -Direct restorations for anterior and posterior teeth (Class I-III Cavities, cervical caries, root erosion), cavity base/liner, intraoral repairs of fractured crowns/bridges/composite resin		
			Alloy Primer	Intended Use adhesion of metal inlays, onlays, crowns, bridges and metal posts, repair of fractured resin based facing crowns and porcelain fused metal crowns and bridges, fabrication of removable		
			Caries Detector	Intended use detects carious dentine for cavity preparation		
			Ceramic Primer	Intended use surface treatment of porcelain, ceramics, hybrid ceramics or composite resin, intra-oral repairs of fractured crowns/bridges made of porcelain, ceramics, hybrid ceramics, hybrid ceramics or		
			Clearfill SA Luting	Intended Use Cementation of crowns, bridges, inlays and onlays, made of ceramic (such as zirconia and alumina), composite resin on metal, cementation of metal cores, resin cores, metal posts or glass fiber		
			Clearfill Photo Bond	Intended Use-Enamel and dentin bonding agent for direct composite restorations		
49	29/Misc/03/2018-DC (176)	M/s A V Medical Systems, 18,1st Floor, B1/16,New Kondli, Mayur Vihar, Phase-III, Delhi-110096	Surgical Incision Closure	Intended for surgical closure as Class B device under the provision of D & C Act and MD Rules 2017	Not Notified	11.05.2018
			Drainage Tube Fixing	Intended to fix Drainage catheters and ventilation mask used during endoscopy allowing intraprocedural treatment of respiratory complications without interrupting the procedure		
50	29/Misc/03/2018-DC (192)	M/s Cook India Medical Devices Pvt.Ltd., 4/249-A, Rasim Enclave, Poonamallee High	Tissue grafts, staple line reinforcement and dural grafts derived from animal origin	Intended to reinforce soft tissue and as a substitute for repairing dura matter	Regulated	11.05.2018
51	29/Misc/03/2018-DC (128)	M/s Premier Enterprises, No.39/2, South Street, Chatrapatti-626102, Via Rajapalayam, Tamil Nadu	DeRoyal Solidifier	Intended to be used to quickly and completely solidify blood and body fluids for disposal	Not Notified	15.05.2018
			Safeliner semi-rigid liner system	Intended to be used to aid in the management and disposal of waste fluid during variety of medical procedures		
52	29/Misc/03/2018-DC (159)	M/s Nobel Biocare, UnitNo.702,7th floor,A Wing, Supreme Business Park, Supreme	AdvanSync 2 (Orthodontic Dental Bracket)	Intended to be used during orthodontic treatment to move the teeth	Not Notified	15.05.2018
53	29/Misc/03/2018-DC (158)	M/s Nobel Biocare, UnitNo.702,7th floor,A Wing, Supreme Business Park, Supreme	Orthodontic Dental Bracket	Intended use during orthodontic treatment to move teeth	Not Notified	15.05.2018
54	29/Misc/03/2018-DC (205)	M/s Medcom International Eyetech Pvt.Ltd., 305-C, Iris Tech Park, Sohna Road, Sector-48, Gurmaon-	Evolve Eye Mask (Reusable moist heat mask)	Intended for soothing relief for tired and sore eyes and soothing relief for gritty sensation or irritation on the external closed eye surface	Not Notified	15.05.2018
55	29/Misc/03/2018-DC (204)	M/s Conva Tech India Pvt.Ltd., SY No.217, Next Logistics Dock -4, Soukya Road, Next to Police	Unometer Safeti Plus containing tubing and urinary drainage bag without catheter	Intended for collection and measuring the urine volume output in critically ill patients	Not Regulated	15.05.2018
56	29/Misc/03/2018-DC (22)	M/s Digital e-Life Pvt.Ltd., Kamalini Building, Top Floor, Central Avenue Road, Chembur (E) Mumbai-	Hydropumps, Vibe Rings, Power Rings and related accessories	Intended for non medical use	Not Regulated	15.05.2018
57	29/Misc/03/2018-DC (210)	M/s BSN Medical Pvt.Ltd., B-10, Lotus Park, Jay Coach Junction, Opp.Raheja Ridgewood, Jogeshwari-	LeukoFix and Fixomull Gentle Touch dressing	Intended for holding or fixation of dressings, catheters, IV Tubes, cannulae, etc.	Not Regulated	22.05.2018
58	29/Misc/03/2018-DC (217)	M/s Riddhi Associates, B-276, Okhla Industrial Area, Phase-1, New Delhi-110020	MiniMizer Gastric Ring	Intended to be used in gastric bypass and sleeve gastrectomy operations, for sustained and effective weight loss in bariatric surgery	Not Notified	22.05.2018

59	29/Misc/03/2018-DC (164)	M/s Intuitive Surgical India Pvt.Ltd.,C/o Regus Suburb Centres Pvt.Ltd., Level-4 Dynasty, A-Wing, Andheri. The Drugs Controller, Govt. of Rajshthan, Drug Control Organization, Swasthya Bhawan Tilak Maro Room	Instrument Arm Drape, Camera Arm and Head Drape, Column Drape and Arm 4 Extension Drape, Mucus extractor, Double Stent, Abdominal Drain Kit having drainage catheter and collection bag	Intended to maintains terility of the sterile field when non sterile prtions of the da vinci Xi System (IS4000 Surgical System) enter the sterile field by covering the parts of instruments	Not Regulated	24.05.2018
60	29/Misc/03/2018-DC (230)			Nil	Regulated	24.05.2018
61	29/Misc/03/2017-DC (334)	M/s Glowtronics Pvt.Ltd., 1D, Hootagalli Industrial Area, Mysore-570018, India	Laposcopic Grasper	Intended to grasp tissue, retrieve foreign bodies and remove tissues from within the gastrointestinal tract	Regulated	28.05.2018
			Single use Biopsy Forceps	Intended to collect tissue or foreign body retrieval, from Gastrointestinal tract using an endoscopy		
			Multiple Band Ligator	Intended for endoscopic ligation of oesophageal varices and anorectal haemorrhoids		
62	29/Misc/03/2018-DC (206)	M/s BSN Medical Pvt.Ltd., B 10, Lotus Park, Jay Coach Junction, Opp. Raheja Ridgewood, Jogeshwari-400063, Maharashtra	Delta Dry Stockinetter	Intended to be used for the protection of skin udnercasting materials	Not Regulated	30.05.2018
			Delta Dry Reyonsa	Intended to be used to keep the skin dry		
63	29/Misc/03/2018-DC (181)	M/s Medicom International Eyetetch Pvt.Ltd., 305-C, Iris Tech Park, Sohna Road, Sector-48, Gurmaan-	E>Eye Medical Equipment	Intended to treat dry eye syndrome	Not Notified	06.06.2018
64	29/Misc/03/2018-DC (246)	M/s GPC Medical Ltd., M Block, DDA, LSC, Vikas Puri, New Dlehi-110018	Oxygen Catheter	It is used for direct administration of oxygen through the naso pharynx.	Regulated	13.06.2018
			Kehr's T Tube	It is used for short term post-operative drainage of common bile duct.		
			Female Catheter	It is used for short term bladder catheterisation through urethra in females.		
			Chest/Thoracic Drainage Catheter	It is used for post operative drainage after cardio thoracic surgery.		
			Thoracic Trocar Catheter	It is used for rapid non operational pleural and chest drainage.		
			Mucus Extractor	It is used for aspiration of secretion from oropharynx in newly born babies.		
			Redon Drainage Catheter	It is an effective device for close wound drainage under negative pressure with the option to use one catheter or two catheter simultaneously.		
			Yankaur Suction set	It is used for removal of secretion and blood pass during surgical procedure		
			Pressure monitoring line	It is used for high pressure monitoring and connection between syringe and infusion pump.		
Male external catheter	It is used for urine incontinence in male patient					
65	29/Misc/03/2018-DC (252)	M/s Bio India Interventional Technolgoies Pvt.Ltd., Plot No.14, Unit A-2, Near Charak	Oactive Knee Brace	Inetnded for mild to severe unicompartmental knee osteoarthritis	Not Regulated	13.06.2018
66	29/Misc/03/2018-DC (182)	M/s Tripod Healthcare Pvt.Ltd., 3, Circus Range, Kolkata-700019, West Bengal India	Smarport Disposable Paproscopic Access System is a sterile device containing a path of entry	Intended to be used for creating a path of entry through tissue planes and or potential spaces and maintain a working channel for the passagage of laparoscope/endoscope/instrument/device for EDTA Cream used to clean root canal of pulp, blood vessels, nerve net using a roatry root canal isnrument by removing inorganic sustance by chelation action nly used for cleaning purposes. will Used to cleanse the root canal, is in liquid form and removes the inorganic substance from the root canal. Only used for cleaning purposes, will remain in the root canal	Regulated	13.06.2018
			MD-Chel Cream	Used to cleanse the root canal, is in liquid form and removes the inorganic substance from the root canal. Only used for cleaning purposes, will remain in the root canal		
			MD-Cleanser	Resin based root canal cemen.Allows creation of hermetic seal of root canal/		
			Adseal Resin based root canal sealer	Used to fill the root canal after cleaning and shaping the root canal		
			Gutta Percha Points			

67	29/Misc/03/2018-DC (55)	M/s Confident Sales India Pvt.Ltd., No.47,2nd floor, Pete Channappa Industrial Estate, magadi Main Road, Kamakshipalya, Bangalore-560079	Absorbent Paper Points	Used to dry the root canal	Not Regulated	14.06.2018
			Metapex Calcium Hydroxide with Iodoform	Premixed paste, radio-opaque, provided in Syringe for easy delivery of the paste to the Canal		
			NexPost Fiber Post	Glass Fiber Post, light translucency for efficient light cure deep into the root canal & optimal Flexural Strength (close to dentin)		
			NexCore Dual Cured core build Up material	To restore lost tooth structure, strong cement helps build it		
			MD-Temp Plus Hydraulic Temporary Restorative	Temporary filling material used to close the cavity after tooth cutting		
			NETC Non-Eugenol Temporary Cement	Contains Zinc Oxide, Spontaneous setting. Material use to make a temporary crown until permanent crown can be prepared		
			Meta Etchant	Use for conditioning of dentin surface so that later the filling will adhere to the tooth. Also for conditioning Enamel to fix Inlay/Onlay on the tooth		
			Meta P & Bond	Bonding for porcelain, direct composite, metal Repair, set amalgam and post		
			Biner LC	Used as a cavity liner before making permanent. Filling this has better thermal conductivity. It also stimulates formation of secondary dentin		
			Nexcomp	Used for composite & porcelain repairs, allows optimum handling, excellent sculptability for restoring natural shape & function		
Nexcomp Flow	Low viscosity, light-cured, radio-opaque flow able composite resin for minimally invasive cavity preparation.					
68	29/Misc/03/2017-DC (331)	M/s Mysore Wilfronics Pvt.Ltd., A-4A, Hootagalli Industrial Area, Mysore-570018, Karnataka, India	Turp (Transurethral Resection of Prostate) Loops	Intended to Reduce the Size of prostate gland entering through urinary tube of male patients by removing abnormal tissues (Class C)	Regulated	14.06.2018
			Diathermy Loops	Intended for excision, coagulation or electro-coagulation of abnormal tissue, growth or lesions in the cervix called cervical intraepithelial neoplasia (CIN) and HPV related condylomata acuminata. Intended for surgery in conjunction with surgical septoplasty under anesthesia using endoscopy and incision in lining tissue around tubinate by cauterizing with radio frequency or electrical current.		
			Tubri-bi-probe	Intended for procedure to dissolve scar tissue around entrapped nerves in the Epidural Space of spine to enable reach of cortisone into affected areas. The procedure involves inserting the function part of the		
			Resaflex Probe	Intended for procedure to dissolve scar tissue around entrapped nerves in the Epidural space of spine to enable reach to cortisone into affected areas. The procedure involves inserting the function		
			Resadisc Probe	Intended for procedure to dissolve scar tissue around entrapped nerves in the Epidural space of spine to enable reach to cortisone into affected areas. The procedure involves inserting the function		
Lap Loop	Intended for Amputates the uterine corpus from the cervix during laproscopic supracervical hysterectomy (Class c)					
69	29/Misc/03/2018-DC (268)	M/s Septodont Healthcare India Pvt.Ltd., C-1/2, MODC, Talaja, Panvel, Dist. Raigad-410208	septo etch, secure Bond, Endure Nano and Endure Flow	Used for restoration of tooth	Not Regulated	19.06.2018
70	29/Misc/03/2018-DC (269)	M/s Koye Pharmaceuticals Pvt.Ltd., A-10, Art Guild House, Phoenix Market City Annex, LBS Marg, Shri Saunni Gandhi, 7/159, Jain Paradise, Jain Society, Sion (Wests) Mumbai-400022	Lubo Airway Collar	Intended for open airway and immobilization of the cervical spine in traumatic patients on emergency situations	Not Regulated	19.06.2018
71	29/Misc/03/2018-DC (277)	M/s Datt Mediproducts Pvt.Ltd., 56, Community Centre, East of Kailash, New Delhi-110065	Oximeter, Nebulizer, Bed Wetting alarm and Air Pollution	Nil	Not Regulated	22.06.2018
72	29/Misc/03/2018-DC (186)	M/s TS Comprozone Pvt.Ltd., Office No.1, Swaralata Apt., Off Gokhale Road	Bovine Thrombin Powder used for manufacturing haemostatic patch	Intended for topical dressing for emergency use in case of severely bleeding wounds	Does not have predicate device and it required permission from this office under D & C Act and Rules	27.06.2018
73	29/Misc/03/2018-DC (227)	M/s Agastya Software Pvt.Ltd., Office NO.121, Corethum, Plot NO A-41 Sector-62 Noida-	Endovenous laser therapy	Endovenous laser therapy of Varicose Veins using laser pulse	Regulated Under Ablation Device as Class C Device	28.06.2018
74	29/Misc/03/2018-DC (294)	M/s Agastya Software Pvt.Ltd., Office NO.121, Corethum, Plot NO A-41 Sector-62 Noida-	Pocket ECG Device -Sanker Life	Intended to Monitor ECG	Not Regulated	28.06.2018
			External Eyelid weight	Intended for lagophthalmos for temporary facial paralysis or bell's palsy		

75	29/Misc/03/2018-DC (255)	M/s Carl Zeiss India (Bnagalore) Pvt.Ltd., Plot NO.3, Block 2,Vision Jigani Link Road, Bommasandra Industrial Area,banaglore-560099	Eyelid weight implants Ptose- up Ptosis Probe Symblepharon Ring Metaireau Tubes	Designed for the gravity-assisted treatment of the functional defects of lagophthalmos resulting from facial paralysis. The implantation of a weight implant allows a passive reanimation of the eyelid to correct Surgical treatment of ptosis requiring brow suspension, where levator palpebrae are unusable. The band is placed between the tarsal plate and occipitofrontalis muscle. Surgical treatment of ptosis requiring brow suspension and Ptosis probe is autogenous or homologous materials offer the following advantages such as reduced operation and hospitalization time. Implantable device as circular band used to prevent the eyelid from adhering to the eyeball and occasionally for glaucoma.Prevent the retraction of the conjunctival culs-de-sacs.The Wide central hole It is used for lacerhinostomy derivation between the internal canthus and the nasal fossa Dacryocystorhinostomy (conventional or laser).	Not Regulated	03.07.2018
76	29/Misc/03/2018-DC (281)	M/s Geetha Manunath,PhD, Co foudner CEO,Niramal Health Analytix Pvt.Ltd., A7-506 Flita Promenade ,JP	Thermalytix,a non -invasive device	Intended to be used for Diagnostics of breast cancer	Not Notified	05.07.2018
77	29/Misc/03/2018-DC (12)	M/s Reckitt Benckiser (India)pvt.ltd., Plot No.48,Sector-32 Institutional area	Durex Play Lubricant	Intended to ease vaginal dryness and intimate discomfort and applied to intimate areas prior to sexual intercourse	Under the definon of Drug/New Drug	05.07.2018
78	29/Misc/03/2018-DC (241)	M/s. Cloudncare E-Health Pvt.Ltd., A-402 Ridgeview, IFS Society, Sector 54 Gurgaon-122011	Virtual Reality anatomy 3D Visualization table	Intended for medical imaging, digital learning, peroperative image analysis and simulation	Not Notified	18.07.2018
79	29/Misc/03/2018-DC (347)	M/s Clinixperts Sservices Pvt.Ltd., Unit No.325,City Centre mall, Plot No.5.Sector-	Negative pressure wound therapy device	Used to enhance and promote wound healing in acute, chronic and burn wounds	Regulated	20.07.2018
80	29/Misc/03/2018-DC (225)	M/s Carl Zeiss India (Bnagalore) Pvt.Ltd., Plot NO.3, Block 2,Vision Jigani Link Road, Bommasandra Industrial Area,banaglore-560099	Lacrimal Dialator and probes Punctum Dilator and Plug Inserter Disposable Iris Retractor Sizer for autostbale intubation set II Sizers Set	Used for exploring the lacrimal canal (the lacrimal duct) during an ophthalmic procedure Facilities the insert plug portion of all monocanalicular intubation systems into punctum Used for the temporary mechanical dilatation of the margins of the iris during ophthalmic surgery Enables to choose the appropriate length of masterka or autostable bicanaliculus intubation set II Determine the proper orbital implant diameter for enucleation or evisceration	Not Regulated	23.07.2018
81	29/Misc/03/2018-DC (170)	M/s NovoMed Incorporation Pvt.Ltd., Shop No.103,the Summit Business BayPrakashwadi Near	NATROX Oxygen wound therapy system	Intended for wound hearing	Regulated	23.07.2018
82	29/Misc/03/2018-DC (326)	M/s Lexir Resources Pvt.Ltd., 101,Vatika Business Park,Tower-2, Sohna Road,Sector-	Artifical Teeth (HS Code 90212100) (Customized dental crowns and bridges)	Nil	Not Notified	23.07.2018
83	29/Misc/03/2018-DC (329)	M/s Convatec India Pvt.Ltd., SY No.217,Next Logsitics Dock -4,Soukya Road, Next to police station korallur	Sensi Care Sting Free Adhesive Releaser Spray	Intended to be used for atraumatic removal of medical adhesives,wound dressings and appliances	Not Notified	23.07.2018
84	29/Misc/03/2018-DC (316)	M/s Skylabz, Plot No.3/156/4D,SKS Nagar, Ayya Ramasubbu Lane,Pandikovli ring road, madurai-625020,TN	Inflation device Torque Device	Intended to be used for inflating the balloon or stent during angioplasty by creating positive pressure connected to stent delivery catheter Intended for holding and twisting guidewire during interventional procedures	Regulated Not Notified	23.07.2018
85	29/Misc/03/2018-DC (325)	M/s Haitech Medical Solutions Pvt.Ltd., 510,Bhaveswar Arcade, Annex Area, Opp Shreyas Cinema, Behind Sarawat Copoerative bank,lbs road, Mumbai	Orthomta RetroMTA	Intended for root canal grafting for repair of root perforations, internal resportion and apexification Intended for vital pulp therapy for deciduous and young teeth and repair material for permanent teeth	Not Regulated	24.07.2018
86	29/Misc/03/2018-DC (333)	M/s Convatec India Pvt.Ltd., SY No.217,Next Logsitics Dock -4,Soukya Road, Next to police station korallur	Sensi Care Sting Free Skun barrier Spray	Intended for the protection of damaged at risk and peri wound skin from the detrimental effects of body waste, enzymes and adhesives	Not Notified	24.07.2018
87	29/Misc/03/2018-DC (343)	M/s FCL Vision (OPC) Pvt.Ltd., D3-Block ,B-1,KH No.69,1st floor, Mahavir Enclave, New Delhi-110045	Color Perfection (Theatrical eye accessories) reusable conatct	Intended to enhance or alter the apparent colour of the eye	Not Notified	24.07.2018
88	29/Misc/03/2018-DC (357)	M/s BEMPU Health Pvt.Ltd.,#32, Alsa Glenridge Apartment 3C, 3rd floor, Langford Road, Bangalore-	BEMPU Apne Boot	Intended to be used to detect and correct apnea for pre maturity	Not Notified	24.07.2018

89	29/Misc/03/2018-DC (274)	M/s Clinixperts Services Pvt.Ltd., Unit No.325, City Centre mall, Plot No.5 Sector-	Import Organ Care system	Nil	Under Regulation and in DTAB in its 78th meeting dated 12-02-2018 has recommended to notify the	25.07.2018
90	29/Misc/03/2018-DC (355)	M/s Hollister Medical India Pvt.Ltd., Plot No.27, Sector-5, Phase-II, HSIDC, Growth Center, Bwai-	Stoma Cone Irrigation System	Intended to be used for routine irrigation to regulate emptying of the bowel	Regulated	25.07.2018
91	29/Misc/03/2018-DC (218)	M/s Browndove Healthcare Pvt.Ltd., Plot No.318/A, Harohalli, 2nd phase, Industrial area, kanakapura Taluq., Kamanagar-562112	Dialyzer with Blood tubing set	Intended for filtering the blood	Regulated	26.07.2018
			Yankauer suction Set	Intended for suctioning of secretions, blood and debris peri-operatively		
92	29/Misc/03/2018-DC (359)	M/s Montra Healthcare Pvt.Ltd., 202, Mani Niketan, Plot No.496, Defence Colony, Sainikpuri	ECG Monitor (upBeat), a non-invasive adhesive sensor patch	Intended to be used for detection of heart rhythm disorders	Not Notified	27.07.2018
93	29/Misc/03/2018-DC (358)	M/s Orbit Lifesciences, Mehtra Mahal, 7th floor, 15, mathew road, opera house mumbai-400004	NeoDiamond Burs	Intended to be used to cut and drill the teeth for root canal treatment	Not Notified	27.07.2018
94	29/Misc/03/2018-DC (342)	M/s Romsons Medicons, E-20, Foundary Nagar, Agra-282006	High Concentration Oxygen Mask, Oxygen Mas and Nebulizer	Intended for delivering oxygen and medication to treat respiratory disorders	Not Regulated	31.07.2018
95	29/Misc/03/2018-DC (328)	M/s Romsons Medicons, E-20, Foundary Nagar, Agra-282006	Nasal Oxygen	Intended for delivering oxygen for inhaling small amount of supplement	Regulated	31.07.2018
			Umbilical cord clamp	Intended to clamp over the newborn infants umbilical cord after delivery and prevent the blood loss		
96	29/Misc/03/2018-DC (352)	M/s Evelabs Technologies Pvt.Ltd., V V Nivas, Archal Nedyara, P.O., Anchal Kollam Kerala-691306	Dripo Smart Infusion Monitor	Intended to be used as supplementary electronic drip monitor in standard gravity infusion and set gravity infusion rates (Flor Regulation)	Regulated	31.07.2018
97	29/Misc/03/2018-DC (366)	M/s Siddhivinayak Healthcare, 34, Snehkunj Society, Part-2, Near Isanpur Bus Stand, Ahmedabad-43	ECG Gel	Intended to support the quality of electrical connection between devices and the human body	Not Notified	03.08.2018
			Ultrasound Gel	Intended to be used as a non sterile transmission medical for acoustically coupling a transducer to a human body surface during external, diagnostics ultrasound imaging procedures		
98	29/Misc/03/2018-DC (299)	M/s B Braun Medical (India) Pvt.Ltd., 2nd Floor, 30 & 30E, Shivaji Marg, Najafgarh Road New Delhi-	Forceps	Intended to hold object with any attachment to catheter	Not Regulated	03.08.2018
99	29/Misc/03/2018-DC (258)	Parsanthi Nilayam-515134, Anapatur Dist Andhra Pradesh	Trust Vide Shipment No.41-SSSCTC-Whitefield	Donation Purpose	Not Regulated	06.08.2018
100	29/Misc/03/2018-DC (297)	M/s Regency Lifesciences India Pvt.Ltd., #8, 4th A Cross, 5th Main Road, HBRR 2nd Block	Duragraft	Intended for preservation, storage and flushing to maintain the structural and functional integrity of saphenous veins prior to grafting in coronary artery bypass surgeries	Under Regulation	06.08.2018
101	29/Misc/03/2018-DC (368)	M/s Spovum Technologies Pvt.Ltd., 19, 20th Main Road, Padmanabha Nagar, Bangalore-560070	RoboCSI an indigenously developed MD	Intended to be used to hold the oocyte during sperm injection	Not yet Notified	06.08.2018
102	29/Misc/03/2018-DC (369)	M/s LivaNova India Pvt.Ltd., 807, 8th floor, new delhi house, barakhama road new delhi-110001	Hemoconcentrator	Intended for cardiopulmonary bypass circuits for hemoconcentration	Regulated	07.08.2018
103	29/Misc/03/2018-DC (371)	M/s THE Knowledge Solutions, 280, 59th Cross, 17th C Main, 3rd Y Block, Rajaji Nagar Bangalore-	ENOBIO Wireless EEG Device	Intended to reproduce EEG, EOG, EMG and ECG signals with quantitative EEG Capabilities and optional GSR Monitoring	Not yet Notified	08.08.2018
104	29/Misc/03/2018-DC (367)	M/s Turoen Medical Device India Pvt.Ltd., Plot No.23, Upeer Floor, BLK, Pkt 6, Sector-15, Roini-110085	Disposable Blade (mouth piece)	Intended to be used with video laryngoscope used to obtain clear view of the vocal cords and to assist in the insertion of a tracheal intubation during surgical procedures	Not Notified	09.08.2018
105	29/Misc/03/2018-DC (319)	M/s Boston Scientific India Pvt.Ltd., C-40/41, Ground Floor, Okhla Industrial Area, Phase-II, New Delhi-110020	RF Generator	Provides controlled delivery of RF Energy to the catheter/cannula/electrode etc.	Regulated	09.08.2018
			Patient Return Electrode	It is placed on the patient's skin to complete the return path for electric current		
			Laser Fibers	Transmits laser energy from the laser console to the treatment site		
			Laser Console	Emits laser radiation to laser fibers		
			Punctum Plugs	Designed to close the lacrimal puncta in the treatment of dry eye		

106	29/Misc/03/2018-DC (147)	M/s Carl Zeiss India (Bnagalore) Pvt.Ltd., Plot NO.3, Block 2,Vision Jigani Link Road, Bommasandra Industrial Area,banaglore-560099	Punctual Stenosis	Used to treat excessive tearing due to partial occlusion of punctum and punctual stenosis.	Regulated	10.08.2018
			Monocanalicular Intubation	Self-retaining punctual fixation of the treatment of monocanalicular lacerations and stenosis.		
			Monocanalicular Nasolacrimal Intubations	Treatment of monocanalicular lacerations and stenosis requiring intubation.Congenital lacrimal duct obstructions, canalicular agenesis (stenosis of the valve of Hasner) in patients 12 months and indicated for treatments of epiphora in adults.		
			Bicanalicular Intubation	particularly in cases of: Meatic pathologies (meatic atresia) ,Canalicular pathologies (canalicular stricture)		
			Bicanalicular Nasolacrimal Intubation	indicated in treatments of: canalicular pathologies (stenosis, obstruction),dacryocystorhinostomy (standard or laser) ,Imperforation of the nasolacrimal duct in infants Nunchaku		
Ophthacath	Lacrimal duct catheter intended for use during dilation of the obstructed nasolacrimal duct to treat Epiphora.The lacrimal duct catheter is indicated:For patients 12 months of age and older as a primary					
107	29/Misc/03/2018-DC (372)	M/s Reliance Life Sciences Pvt.Itd., R-282,TTC Area of MIDC, Thane-Belapur Road, Rabale Navi Mumbai	Prefillable Glass Barrel with needle (Sterile)	Intended to be used as a component of disposable system for packaging and administration of parenteral drugs	Regulated	10.08.2018
108	29/Misc/03/2018-DC (126)	M/s Shaili Endoscopy ,Plot No.210 &213, Padara Jambusar Road, Dabhasa, Padra,Vadodara-391440,Gujarat	Lithobasket	It is used endoscopically to remove stone from common biliary duct (CBD)	Regulated	13.08.2018
			Pancreatic Basket	It is used endoscopically to remove stone from common duct		
			Choledoch Basket	It is used to remove bile duct stone through choledoch scope		
			2 Stage Dilator	It is used endoscopically to dilate strictures of the Gastrointestinal tract		
			Hot Biopsy Forceps	It is used endoscopically to obtain mucosal tissue samples from gastrointestinal tract		
109	29/Misc/03/2018-DC (12)	M/s Reckitt Benckiser (India)pvt.ltd., Plot No.48,Sector-32 Institutional area	Durex Play Lubricant	Intended to be used to ease vaginal dryness and intimate discomfort and applied to intimate areas prior to sexual intercourse	Under the definition of Drug/New Drug	13.08.2018
110	29/Misc/03/2018-DC (339)	M/s Lal Pet Products, 24- IDC, Sector-14, Mehrauli Gurgaon Road, Gurgaon-122001 Haryana India	JETT Plasmelift	It is intended to be used for rejuvenating the skin	Not Notified	13.08.2018
111	29/Misc/03/2018-DC (342)	M/s Romsons Medicons ,E-20,Foundary Nagar,Agra-282006	Breathing Circuit	Nil	Not Regulated	17.08.2018
112	29/Misc/03/2018-DC (353)	M/s Oralla Dental Private Limited., B-305,Cello Heights, Opp Laghu Udyog Gurgaon, East	Orthodontic Appliance (Brand Name:-Vincialign)	Intended to be used for the correction of tooth malocclusion in patients with permanent dentition	Not Notified	17.08.2018
113	29/Misc/03/2018-DC (137)	M/s BIBAWO Medical Pvt.Ltd., 53,Green Dargden Apartments, W T Patil Marg, Govandi, Deonar	Hydrozid	Intended to be used for cryotherapy of warts, skin lesions and specific mucosal lesions by freezing the damage tissue with the cryogen HFC-134a based on the mechanism of ablation (ABLATION DEVICE)	Regulated	21.08.2018
114	29/Misc/03/2018-DC (96)	M/a All India Surgicals, Moh, Pirthvi Ganj, Kanth,Distt Moradabad-244001,Uttar Pradesh,India	Absorbent Cotton Wool	Intended to be used for cleaning of wound (SURGICAL DRESSING)	Regulated	21.08.2018
			Crepe Bandage	Intended to be used to treat muscle sprains and strains by the application of even stable pressure	Not Regulated	
115	29/Misc/03/2018-DC (119)	M/s Johnson and Johnson Pvt.Ltd., LBS Marg, Mulund (West), Mumbai-400080	Sterrad Cassette	Intended to be used as sterilant for sterilization of medical equipments and devices	Not Notified	24.08.2018
116	29/Misc/03/2018-DC (372)	M/s Tuoren Medical Device India pvt.Ltd., Plot No.23, Upper Floor,BLK B Pkt 6, Sector-15 Rohini-110085 The Deputy Trade	Loss of Resistance (LOR) indicator syringe	Intended for epidural anesthesia, combined spinal epidural anesthesia to indicate that the epidural needle reaches the epidural space (DISPOSABLE HYPODERMIC SYRINGE)	Regulated	04.09.2018
117	29/Misc/03/2018-DC (376)	Commissioner, The Trade representation of the Russian Federation in the	Lung Ventilator	Intended to provide non invasive breathing support and lung ventilation to patient	Not Notified	06.09.2018
118	29/Misc/03/2018-DC (340)	M/s Wrig Nanosystems Pvt.Ltd., Plot No.170,2nd Floor, Patparganj Industrial Area, New Delhi-110092	Lancet	Intended to be used to make punctures to obtain small blood specimens	Not Regulated	06.09.2018
			Lancing Device	Intended to be used for blood sampling equipped with a lancet		

119	29/Misc/03/2018-DC (376)	M/s Ajay Industrial Corporation Ltd., B-11, Mohan Co-Operative Industrial Estate, Badapur	Relief Pad	A reusable sanitary pad intended for collecting menstrual blood	Not Notified	10.09.2018
120	29/Misc/03/2018-DC (383)	M/s Ucrest Berhad (420056-K) (formerly known as Palette Multimedia Berhad), 6th Floor, Unit -4 8 First	Ekectostimulator	Intended for arterial blood preesure correction	Not Notified	10.09.2018
121	29/Misc/03/2018-DC (360)	M/s GC Chemia Pharmie Ltd., 5/C, Shree Laxmi Indl., Estate, New Link Road, Andheri (East), Mumbai-400053	Ecotin Ellergy Nasal Spray 2%	Intended to be used for treatment and prevention of of non allergeric rhinitis or rhinosinusitis associated with common cold and product	Not Notified	12.09.2018
			Ecotin Inhalation Solution	Intended to be used for daily basic therapy of airway diseases such as bronchitis, chronic obstructive pulmonary disease (COPD) or asthma		
122	29/Misc/03/2018-DC (126)	M/s Meril Life Sciences Pvt.Ltd., Survey No.135/2a,174/2 (M1-M2 meril Park), Near	Coblation Wand	Intended to be used for ablation, resection and coagulation of soft tissue and hemostasis of blood vessels in ENT surgeries i.e. Tonsillectomy and adenoidectomy	Regulated	12.09.2018
123	29/Misc/03/2018-DC (376)	M/s Sugnovate Technoloies Pvt.Ltd., A4-711, Sobha Anvamarine Bellandur Bengaluru	Hynto	Intended to be used for monitoring hygiene condition inside baby's diaper	Not Regulated	26.09.2018
124	29/Misc/03/2018-DC (49)	M/s Septodont Healthcare India Pvt.Ltd., C-1/2, MODC, Talaja, Panvel, Dist. Raigad-410208	Biodentine	Intended for sealant of dental crowns on the dentine surface maintaining the pulp vitality	Not Notified	27.09.2018





































