



FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2021/000297

1. M/s DEVON INNOVATIONS PVT LTD, 27A ELECTRONIC CITY PHASE 1 BANGALORE, Bengaluru (Bangalore) Urban, Karnataka (India) - 560100 Telephone No.: 080 28522367 FAX: 080 28522370 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Devon Innovations Private Limited, No.27A, Near State Bank of India, Electronics city, Phase-1, Hosur road, Bangalore, Bengaluru (Bangalore) Urban, Karnataka (India) - 560100 Telephone No.: 080-28522367, 368 FAX: 080-28522370

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name: Fine needle aspiration catheter (FNAC) Model No.: NIL Intended Use: Used to investigate superficial lumps or masses Class of medical device: Class B Material of construction: Stainless steel Dimension (if any): 14G-12, 15, 21CM, 16G-15, 21, 35CM, 17G-15, 21CM, 18G-15, 21CM, 20G-15, 21, 35CM, 21G-15, 21CM, 22G-15, 21CM Shelflife: 3 Years Sterile or Non sterile: Both Brand Name (if registered under the Trade Marks Act, 1999): DEVON
2	Generic Name: Biliary Duct Drainage Catheter (BDDC) Model No.: NIL Intended Use: Used for trans-hepatic biliary drainage. Class of medical device: Class B Material of construction: Medical Grade Polyurethane Dimension (if any): 6F/50CM, 8F/50CM, 10F/50CM, 12F/50CM, 14F/50CM, 16F/50CM, 18F/50CM and other Dimensions Shelflife: 5 Years Sterile or Non sterile: Both Brand Name (if registered under the Trade Marks Act, 1999): DEVON

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ou=MARKETING, postalCode=560001,
st=Karnataka,
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9, cn=AMARESH TUMBAGI
Date: 2021.09.13 15:00:49 +05'30'

3	Generic Name:Percutaneous Pigtail Nephrostomy catheter/Set(PTDC/ PCNS) Model No.:NIL Intended Use:Used for temporary or permanent drainage of urine from the kidney Class of medical device:Class B Material of construction:Medical Grade Polyurethane Dimension(if any):5F/25,30,35CM, 6F/22,25,30,35CM, 7F/22,25,30,35CM, 8F/22,25,30,35,40CM, 8.5F/25,30,35CM, 9F/22,25,30,35CM 10F/22,25,30,35CM, 12F/22,25,30,35CM 14F/22,25,30,35CM, 16F/22,25,30,35CM 18F/25,30,35CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
4	Generic Name:External Biliary Drainage Catheter(EBDC) Model No.:NIL Intended Use:Used for temporary drainage of the biliary duct Class of medical device:Class B Material of construction:Medical Grade Polyurethane Dimension(if any):7F/25,50CM, 8F/25,40,50CM, 10F/25,40,50CM,12F/25,50CM,14F/25,50CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
5	Generic Name:IUI Catheter/Cannula(IUI) Model No.:NIL Intended Use:Used for introduction of washed spermatozoa into the uterine cavity. Available in both straight and curved options. Class of medical device:Class B Material of construction:Medical Grade Polypropylene,low density polyethylene Dimension(if any):6F-11CM, 6/8-11 cm/ 7.5 cm, 12 cm/ 9cm,12 cm/ 15cm,14 cm/ 10.5 cm,17 cm/ 12 cm,17.3 cm/ 13 cm and other dimensions Shelflife:3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
6	Generic Name:Percutaneous Malecot Nephrostomy Catheter/Set(MNDC/PCMS) Model No.:NIL Intended Use:Used for nephrostomy drainage in the renal pelvis. Class of medical device:Class B Material of construction:Polyvinyl chloride/ Ethylene-vinyl acetate & Medical Grade Polyurethane Dimension(if any):8F/20,30CM, 10F/16,20,30CM, 12F/20,30CM 14F/20,30CM, 16F/20,30CM, 18F/20,30CM 20F/30,40CM, 22F/30CM, 24F/30CM 26F/30CM, 28F/30CM, 30F/30CM and other Dimensions Shelflife:3 & 5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON

7	Generic Name:Naso Biliary Drainage Catheter(NBDC) Model No.:NIL Intended Use:Used for temporary drainage of the biliary duct Class of medical device:Class B Material of construction:Medical Grade Polyurethane Dimension(if any):5F/200,220,250CM, 6F/200,220,250CM, 7F/200,220,250CM 8F/200,220,250CM, 10F/200,220,250CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
8	Generic Name:Nephrostomy Catheter(NCD) Model No.:NIL Intended Use:Used for drainage of the urine from the bladder at regular intervals Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride Dimension(if any):8F/30,40CM, 10F/30,35,40CM, 12F/20,30,40CM 14F/20,30,40CM, 16F/30,40CM, 18F/30,40CM 20F/30,40CM, 22F/30,40CM, 24F/30,40CM,26F/30, 40CM, 28F/30,40CM 30F/30,40CM and other Dimensions Shelflife:3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
9	Generic Name:Percutaneous Biliary Drainage Catheter/Set(PBDC) Model No.:NIL Intended Use:Intended for percutaneous drainage in a variety of drainage applications Class of medical device:Class B Material of construction:Medical Grade Polyurethane Dimension(if any):5F/32,35,40,42,45CM, 6F/32,35,40,42,45CM, 7F/32,35,40,42,45CM , 8F/32,35,40,42,45CM, 10F/32,35,40,42,45CM , 12F/32,35,40,42,45CM, 14F/32,35,40,42,45 CM, 16F/32,35,40,42,45CM, 18F/32,35,40,42,45CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
10	Generic Name:Pleural Drainage Catheter/ Set(PDC) Model No.:NIL Intended Use:Used to drain fluids Class of medical device:Class B Material of construction:Medical Grade Polyurethane Dimension(if any):8F/60CM,10F/60CM, 12F/60CM,14F/60CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON

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1 1	Generic Name:Suprapubic Cystostomy Catheter/ Set(SPCS) Model No.:NIL Intended Use:Used to provide bladder drainage by percutaneous placement of Malecot catheter Class of medical device:Class B Material of construction:Medical Grade Ethylene-vinyl acetate Dimension(if any):8F/20CM,10F/20CM, 12F/20,30CM, 14F/20CM, 16F/20CM,18F/20CM and other Dimensions Shelflife:3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
12	Generic Name:Tiemman Catheter(TIEM) Model No.:NIL Intended Use:Used to aid in urination for men who have enlarged prostates or suffer from benign prostatic hyperplasia Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride Dimension(if any):8F/20,40CM, 10F/20,30,40CM, 12F/20,30,40CM 14F/20,30,40CM, 16F/20,40CM, 18F/20,40CM, 20F/20,40CM, 22F/20,40CM, 24F/20,40CM and other Dimensions Shelflife:3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
13	Generic Name:Percutaneous Pigtail Suprapubic Catheter / Set(TDCS) Model No.:NIL Intended Use:Used to provide bladder drainage by percutaneous placement of a pigtail catheter. Class of medical device:Class B Material of construction:Medical Grade Polyurethane Dimension(if any):5F/12,22,24,26CM, 6F/12,22CM, 7F/12,22CM, 8F/12,22CM, 8.5F/12,22CM, 9F/12,22CM 10F/12,18,22CM, 12F/12,13,22CM, 14F/12,22CM, 15F/12,22CM, 16F/12,22CM, 18F/12,22CM, and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
14	Generic Name:Ureteral Catheter(UCB/ UOB (WT/AN/PT/CT/MH) Model No.:NIL Intended Use:Used for drainage and retrograde pyelogram Class of medical device:Class B Material of construction:Medical Grade Polyurethane Dimension(if any):3F/45,70CM, 4F/45,50,70CM, 5F/40,45,70CM 6F/45,70CM, 7F/45,70CM, 8F/45,70CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON

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15	Generic Name:Urinary Catheter(CIC-M/F) Model No.:NIL Intended Use:Used for draining urine from the bladder in regular intervals. Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride Dimension(if any):6F/15,25,30,40CM, 8F/15,25,30,40CM, 10F/15,18,25,27,30,40,44CM, 12F/15,18,20,25,27,30,40,44CM, 14F/15,18,20,25,27,30,40,44CM 16F/15,18,20,25,30,40,44CM, 18F/15,25,30,40CM, 20F/15,25,30,40CM 22F/15,25,30,40CM, 24F/15,25,30,40CM and other Dimensions Shelflife:3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
16	Generic Name:Dilator/Set(UD/FDS/ FUD/FD/UDS/SD/MDF/MDM/MDP) Model No.:NIL Intended Use:Used for dilation of the ureter prior to ureteroscopy and/or stone manipulation Class of medical device:Class B Material of construction:Medical Grade Polyurethane, Poly propylene, Ethylene-vinyl acetate, Poly propylene+Ethylene-vinyl acetate Dimension(if any):5F/15,20,22,25,30,70CM, 6F/15,20,22,25,30,70CM, 7F/20,22,25,30,70CM, 8F/20,22,25,30,70CM, 9F/20,22,25,30,70CM, 10F/20,22,25,30,70CM, 12F/20,22,25,30,70CM, 14F/20,22,25,30,70CM, 16F/20,22,25,30,70CM, 18F/20,22,25,30,70CM, 20F/20,22,25,30,70CM, 22F/20,22,25,30,70CM, 24F/20,22,25,30,70CM, 26F/20,22,25,30,70CM 28F/20,22,25,30,70CM, 30F/20,22,25,30,70CM, (12-16)F/8cm,(14-24)F/9cm,(6-16)F/11cm and other Dimensions Shelflife:3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
17	Generic Name:Lung Abcess Drainage Catheter(LADC) Model No.:NIL Intended Use:Used to drain fluides Class of medical device:Class B Material of construction:Medical Grade Polyurethane Dimension(if any):10F/60,80CM, 12F/60,80CM, 14F/60,80CM, 16F/60,80CM and other dimensions Shelflife:4 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
18	Generic Name:Urethral Stent/ Set(US)-(Short/Long Term) Model No.:NIL Intended Use:used for stenting the urethra after hypospadias or epispadias repair and to provide postoperative drainage of the bladder Class of medical device:Class B Material of construction:Medical Grade Polyurethane Dimension(if any):5F/20,25CM, 6F/20,25CM, 7F/20,25CM, 8F/20,25CM, 10F/20,25CM, 12F/20,25CM, 14F/20,25CM, 16F/20,25CM and other dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON

19	Generic Name:Endopyelotomy Stent/ Set(EPEX)(External) Model No.:NIL Intended Use:used for stenting the Ureteropelvic junction and the ureter Class of medical device:Class B Material of construction:Medical Grade Polyurethane Dimension(if any):8/4F-26/26--22,24,26CM, 10/5F-26/26-22,24,26CM, 10/6F-26/26-22,24,26CM, 12/6F-26/26-22,24,26CM, 14/7F-26/26-22,24,26CM, 16/7F-26/26-22,24,26CM, 5/14F-26/26-22,24,26CM, 6/14F-26/26-22,24,26CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
20	Generic Name:Endoureterotomy Stent/ Set(Internal)(EPIN) Model No.:NIL Intended Use:used for temporary drainage from the ureteropelvic junction to the bladder following incision of a stricture Class of medical device:Class B Material of construction:Medical Grade Polyurethane Dimension(if any):8/4F-5/16-16CM, 10/5F-13/22,24,26CM, 10/6-13/26-22,24,26,28CM 10/5.5-13/26 CM 12/6-13/26-22,24,26,28CM 12/7-13/26-24,26CM 14/7-13/26-22,24,26,28CM 14/6-13/26-22,24,26,28CM,16/8F-13/26-26cm and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
21	Generic Name:Amplatz Renal Introducer/ Set(ARI) Model No.:NIL Intended Use:Used for nephrostomy tract dilation and the placement of a stricture Class of medical device:Class B Material of construction:Medical Grade Poly Tetra Fluoro Ethylene Dimension(if any):8F/30CM,10F/30CM,12F/30CM,14F/30CM,16F/30CM,18F/30CM,20F/30CM,22F/30CM,24F/30CM,26F/30CM,28F/30CM,30F/30CM,32F/30CM,34F/30CM and other dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
22	Generic Name:Ureteroscopic Sheath(USH)-M/F Model No.:NIL Intended Use:Ureteral sheaths provide a continual working channel, simplifying ureteroscopic procedures and protecting the ureter during multiple instruments exchanges Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride,Polypropylene Dimension(if any):21F-11CM, 21F-22CM Shelflife:3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON

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Date: 2021.09.13 15:04:43 +05'30'

23	Generic Name:Internal External Drainage Catheter/ Set(IEDC) Model No.:NIL Intended Use:Used for temporary drainage of the biliary duct Class of medical device:Class B Material of construction:Medical Grade Polyurethane Dimension(if any):6F/40,45CM, 7F/30,40,45CM, 8F/40CM, 9F/40CM, 10F/40CM, 12F/40CM, 14F/40CM,16F/40CM, 18F/40CM, and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
24	Generic Name:Cutting Loop – (Single / Double Stem)-CLSS/CLDS Model No.:NIL Intended Use:Used to resect tissue and provide a smooth tissue cut Class of medical device:Class B Material of construction:Stainless steel Dimension(if any):24F-30cm and other dimensions Shelflife:4 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
25	Generic Name:Multi – Band Ligator Barrel(LMB) Model No.:NIL Intended Use:Used to endoscopically ligate esophageal varcies at or above the gastroesophageal junction or to ligate internal hemorrhoids Class of medical device:Class B Material of construction:Latex free protein Dimension(if any):6 bands-122 cm Shelflife:4 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
26	Generic Name:Foreign Body Retriever Dormia Basket(SB)-FLT/SBHEL/SEG/NIT/GRASPER Model No.:NIL Intended Use:Used for stone manipulation and retrieval / removal of Ureteral Stones from the Bladder, Renal Pelvis and Ureter Class of medical device:Class B Material of construction:Stainless steel Dimension(if any):3F-70,90,110CM, 4F-70,90,110CM, 5F-70,90,110CM, 6F-70,90,110CM Shelflife:4 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON

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652289732639, cn=AMARESH TUMBAGI
Date: 2021.09.13 15:05:55 +05'30'

27	Generic Name:Guidewires/zebra Guidewires(GW) Model No.:NIL Intended Use:Guidewires facilitate the delivery of wide variety of Catheters and Stents to a Medical procedure site within the body as a transient use Class of medical device:Class B Material of construction:Stainless steel & Nitinol Dimension(if any):0.018IN/80,150CM, 0.021IN/80,150CM 0.025IN/80,150CM, 0.028IN/80,150CM 0.032IN/80,150,260,400CM, 0.035IN/80,150,260,400CM 0.038IN/80,150,260,400 CM, and other Dimensions Shelflife:3&5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
28	Generic Name:Endoscopic Jejunal Feeding Tube(EJFT) Model No.:NIL Intended Use:Used through the channel of the endoscope to provide short-duration enteral access for delivery of nutrition or medication to the small bowel. Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride & Medical Grade Polyurethane Dimension(if any):10F/150CM, 12F/150CM, 14F/150CM, 16F/150CM and other Dimensions Shelflife:3 & 5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
29	Generic Name:Hemodialysis Catheter Set(HDC) Model No.:NIL Intended Use:Used for exchange blood to and from the Hemodialysis machine from the patient Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride Dimension(if any):11.5F-15cm and other dimensions Shelflife:3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
30	Generic Name:Vario Drain(VD) Model No.:NIL Intended Use:Vario Drain is a Closed Wound Suction Drainage system used after the surgery (Post Surgery) for removing the waste blood & puss from the closed wound. Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride Dimension(if any):7F-620mm,9F-620mm,12F-620mm,14F-620mm,16F-620mm,18F-620mm and other dimensions Shelflife:3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):VARIO DRAIN

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31	Generic Name:Orvac(ORV) Model No.:NIL Intended Use:Orvac is used after the surgery (Post Operative).Closed Wound Suction Drainage System is used for removing the waste blood & puss from the closed wound Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride Dimension(if any):12F-620mm,14F-620mm,16F-620mm,18F-620mm and other dimensions Shelflife:3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):ORVAC
32	Generic Name:Suction Catheter(SC) Model No.:NIL Intended Use:Suction catheters are long flexible tubes that are used in intensive care to remove fluids from the mouth and airways of critically ill patients Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride Dimension(if any):10F/50cm,12F/50cm,14F/50cm,16F/50cm and other dimensions Shelflife:3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):DEVON
33	Generic Name:Klearsite Cannula(KLST) Model No.:NIL Intended Use:Klearsite is used during the surgery (Inter Operative) for removing the waste blood from the wound at the time of surgery & collect that into the suction apparatus. Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride Dimension(if any):10mm & 10.0mm/TC Shelflife:3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):KLEARSITE

Place:

Date:13-Sep-21

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State Licensing Authority

DN: c=IN, o=DRUGS CONTROL
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FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2021/000297

Endorsement No. 1

1. M/s DEVON INNOVATIONS PVT LTD, 27A ELECTRONIC CITY PHASE 1 BANGALORE, Bengaluru (Bangalore) Urban, Karnataka (India) - 560100 Telephone No.: 080 28522367 FAX: 080 28522370 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Devon Innovations Private Limited, No.27A, Near State Bank of India, Electronics city, Phase-1, Hosur road, Bangalore, Bengaluru (Bangalore) Urban, Karnataka (India) - 560100 Telephone No.: 080-28522367,368 FAX: 080-28522370

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Biliary Duct Drainage Catheter(BDDC)-Hydrophilic coated Model No.:NIL Intended Use:Used for trans-hepatic biliary drainage Class of medical device:Class B Material of construction:Medical Grade Polyurethane-Hydrophilic coating Dimension(if any):5F/50CM,6F/50CM,7F/50CM,8F/50CM,10F/50CM, 12F/50CM,14F/50CM, 16F/50CM,18F/50CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
2	Generic Name:Percutaneous Pigtail Nephrostomy catheter/Set(PTDC/ PCNS)-Hydrophilic coated Model No.:NIL Intended Use:Used for temporary or permanent drainage of urine from the kidney Class of medical device:Class B Material of construction:Medical Grade Polyurethane-Hydrophilic coating Dimension(if any):5F/25,30,35,40CM, 6F/25,30,35,40CM, 7F/25,30,35,40CM, 8F/25, 30,35,40CM, 8.5F/25,30,35,40CM, 9F/25,30,35,40CM 10F/25,30,35,40CM, 12F/25,30,35,40 CM 14F/25,30,35,40CM, 16F/25,30,35,40CM 18F/25,30,35,40 CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon

3	Generic Name:External Biliary Drainage Catheter(EBDC)-Hydrophilic coated Model No.:NIL Intended Use:Used for temporary drainage of the biliary duct Class of medical device:Class B Material of construction:Medical Grade Polyurethane-Hydrophilic coating Dimension(if any):5F/25,50CM,6F/25,50CM,7F/25,50CM, 8F/25,50CM, 10F/25,50CM, 12F/25,50CM,14F/25,50CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
4	Generic Name:Percutaneous Malecot Nephrostomy Catheter/Set(MNDC)-Hydrophilic coated Model No.:NIL Intended Use:Used for nephrostomy drainage in the renal pelvis Class of medical device:Class B Material of construction:Polyvinyl chloride/ Ethylene-vinyl acetate & Medical Grade Polyurethane Dimension(if any):8F/20,25,30CM, 10F/20,25,30CM, 12F/20,25,30CM 14F/20,25,30CM, 16F/20,25,30CM, 18F/20,25,30CM 20F/25,30CM, 22F/25,30CM, 24F/25,30CM 26F/25, 30CM, 28F/25,30CM, 30F/25,30CM and other Dimensions Shelflife:3 & 5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
5	Generic Name:Naso Biliary Drainage Catheter(NBDC)-Hydrophilic coated Model No.:NIL Intended Use:Used for temporary drainage of the biliary duct Class of medical device:Class B Material of construction:Medical Grade Polyurethane-Hydrophilic coating Dimension(if any):5F/220,250CM, 6F/220,250CM, 7F/220,250CM 8F/220,250CM, 10F/220, 250CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
6	Generic Name:Nephrostomy Catheter(NCD)-Hydrophilic coated Model No.:NIL Intended Use:Used for drainage of the urine from the bladder at regular intervals Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride-Hydrophilic coating Dimension(if any):8F/30,40CM, 10F/30,40CM, 12F/30,40CM 14F/30,40CM, 16F/30,40CM, 18F/30, 40CM 20F/30,40CM, 22F/30,40CM, 24F/30,40CM,26F/30, 40CM, 28F/30,40CM 30F/30,40CM and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon

7	Generic Name:Percutaneous Biliary Drainage Catheter(PBDC)-Hydrophilic coated Model No.:NIL Intended Use:Intended for percutaneous drainage in a variety of drainage applications Class of medical device:Class B Material of construction:Medical Grade Polyurethane-Hydrophilic coating Dimension(if any):5F/32,35,40,42,45CM, 6F/32,35,40,42,45CM, 7F/32,35,40,42,45CM , 8F/32, 35,40,42,45CM, 10F/32,35,40,42,45CM , 12F/32,35,40,42,45CM, 14F/32,35,40,42,45 CM, 16F/32, 35,40,42,45CM 18F/32,35,40,42,45CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
8	Generic Name:Pleural Drainage Catheter/ Set(PDC)-Hydrophilic coated Model No.:NIL Intended Use:Used to drain fluids Class of medical device:Class B Material of construction:Medical Grade Polyurethane-Hydrophilic coating Dimension(if any):8F/60CM,10F/60CM, 12F/60CM,14F/60CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
9	Generic Name:Suprapubic Cystostomy Catheter/ Set(SPCS)-Hydrophilic coated Model No.:NIL Intended Use:Used to provide bladder drainage by percutaneous placement of Malecot catheter Class of medical device:Class B Material of construction:Medical Grade Ethylene-vinyl acetate-Hydrophilic coating Dimension(if any):8F/20CM,10F/20CM, 12F/20CM 14F/20CM, 16F/20CM,18F/20CM and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
10	Generic Name:Tiemman Catheter(TIEM)-Hydrophilic coated Model No.:NIL Intended Use:Used to aid in urination for men who have enlarged prostates or suffer from benign prostatic hyperplasia Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride-Hydrophilic coating Dimension(if any):8F/20,40CM, 10F/20,40CM, 12F/20,40CM 14F/20,40CM, 16F/20,40CM, 18F/20, 40CM, 20F/20,40CM, 22F/20,40CM, 24F/20,40CM and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon

1 1	Generic Name:Percutaneous Pigtail Suprapubic Catheter / Set(TDCS)-Hydrophilic coated Model No.:NIL Intended Use:Used to provide bladder drainage by percutaneous placement of a pigtail catheter Class of medical device:Class B Material of construction:Medical Grade Polyurethane-Hydrophilic coating Dimension(if any):5F/12,22,24,26CM,6F/12,22CM, 7F/12,22CM, 8F/12,22,25CM, 8.5F/12, 22CM, 9F/12,22CM 10F/12,22CM, 12F/12,22CM, 14F/12,22CM, 16F/12,22CM, 18F/12,22CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
12	Generic Name:Ureteral Catheter(UCB/ UOB-WT/AN/PT/CT/MH)-Hydrophilic coated Model No.:NIL Intended Use:Used for drainage and retrograde pyelogram Class of medical device:Class B Material of construction:Medical Grade Polyurethane-Hydrophilic coating Dimension(if any):3F/45,70CM, 4F/45,70CM, 5F/45,70CM 6F/45,70CM, 7F/45,70CM, 8F/45, 70CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
13	Generic Name:Urinary Catheter(CIC-M/F)-Hydrophilic coated Model No.:NIL Intended Use:Used for draining urine from the bladder in regular intervals Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride-Hydrophilic coating Dimension(if any):6F/15,25,30,40CM,8F/15,25,30,40CM, 10F/15,25,30,40CM, 12F/15, 25,30,40CM, 14F/15,25,30,40CM 16F/15,25,30,40CM, 18F/15,25,30,40CM, 20F/15,25,30,40 CM 22F/15,25,30,40CM, 24F/15,25,30,40 CM and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
14	Generic Name:Dilator/Set(UD/FDS/ FUD/FD/UDS/SD)-Hydrophilic coated Model No.:NIL Intended Use:Used for dilation of the ureter prior to ureteroscopy and/or stone manipulation Class of medical device:Class B Material of construction:Medical Grade Poly propylene, Ethylene-vinyl acetate,Poly propylene+Ethylene-vinyl acetate,Polyurethane-Hydrophilic coating Dimension(if any):5F/20,22,25,30,70CM, 6F/20,22,25,30,70CM, 7F/20,22,25,30,70CM, 8F/20, 22,25,30,70CM, 9F/20,22,25,30,70CM, 10F/20,22,25,30,70CM, 12F/20,22,25,30,70 CM, 14F/20, 22,25,30,70CM, 16F/20,22,25,30,70CM, 18F/20,22,25,30,70CM, 20F/20, 22,25,30,70CM, 22F/20, 22,25,30,70CM, 24F/20,22,25,30,70CM, 26F/20,22,25,30,70CM 28F/20,22,25,30,70CM, 30F/20, 22,25,30,70CM and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon

15	Generic Name:Lung Abscess Drainage Catheter(LADC)-Hydrophilic coated Model No.:NIL Intended Use:Used to drain fluids Class of medical device:Class B Material of construction:Medical Grade Polyurethane-Hydrophilic coating Dimension(if any):10F/60,80CM, 12F/60,80CM, 14F/60,80CM, 16F/60,80CM and other dimensions Shelflife:5 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
16	Generic Name:Urethral Stent/ Set(US)-(Short/Long Term) Hydrophilic coated Model No.:NIL Intended Use:used for stenting the urethra after Hypospadias or Epispadias repair and to provide post operative drainage of the bladder Class of medical device:Class B Material of construction:Medical Grade Polyurethane-Hydrophilic coating Dimension(if any):5F/20,25CM, 6F/20,25CM, 7F/20,25CM, 8F/20,25CM, 10F/20,25CM, 12F/20,25CM, 14F/20,25CM, 16F/20,25CM and other dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
17	Generic Name:Endopyelotomy Stent/ Set(EPEX)(External)-Hydrophilic coated Model No.:NIL Intended Use:used for stenting the Ureteropelvic junction and the ureter Class of medical device:Class B Material of construction:Medical Grade Polyurethane-Hydrophilic coating Dimension(if any):10/5F-26/26,24/26CM, 12/6F-26/26,24/26CM, 14/7F-26/26,24/26CM, 5/14F- 26/26,24/26CM, 6/14F-26/26,24/26CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
18	Generic Name:Endoureterotomy Stent/ Set(Internal)(EPIN)-Hydrophilic coated Model No.:NIL Intended Use:used for temporary drainage from the ureteropelvic junction to the bladder following incision of a stricture Class of medical device:Class B Material of construction:Medical Grade Polyurethane-Hydrophilic coating Dimension(if any):8/4F-5/16, 10/5F-13/22,24,26CM, 10/6-13/22,24,26,28CM 10/5.5-13/26 CM 12/6-13/22,24,26,28CM 12/7-13/24,26CM 14/7-13/22,24,26,28CM 14/6-13/ 22,24,26,28 CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon

19	Generic Name:Internal External Drainage Catheter/ Set(IEDC)-Hydrophilic coated Model No.:NIL Intended Use:Used for temporary drainage of the biliary duct Class of medical device:Class B Material of construction:Medical Grade Polyurethane-Hydrophilic coating Dimension(if any):6F/40CM, 7F/40CM, 8F/40CM, 9F/40CM, 10F/40CM, 12F/40CM, 14F/40CM, 16F/40CM, 18F/40CM, 20F/40CM and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
20	Generic Name:Guidewires(GW)-Hydrophilic coated Model No.:NIL Intended Use:Guidewires facilitate the delivery of wide variety of Catheters and Stents to a Medical procedure site within the body as a transient use Class of medical device:Class B Material of construction:Stainless Steel, Nitinol-Hydrophilic coating Dimension(if any):0.018IN/80,150CM, 0.021IN/80,150CM 0.025IN/80,150CM, 0.028IN/80, 150CM 0.032 IN/80,150,260,400CM, 0.035IN/80,150,260,400CM 0.038IN/80,150,260,400 CM, and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
21	Generic Name:Endoscopic Jejunal Feeding Tube(EJFT)-Hydrophilic coated Model No.:NIL Intended Use:Used through the channel of the endoscope to provide short-duration enteral access for delivery of nutrition or medication to the small bowel Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride, Medical Grade Polyurethane Hydrophilic coating Dimension(if any):10F/150CM, 12F/150CM, 14F/150CM, 16F/150CM and other Dimensions Shelflife:3 & 5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
22	Generic Name:Ureteral Access sheath(UAS)- Hydrophilic coated Model No.:NIL Intended Use:Used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract Class of medical device:Class B Material of construction:Medical Grade Polyurethane-Hydrophilic coating,Stainless Steel Dimension(if any):9.5Fr/11.5Fr – 35,38,45,55 cms, 10.7Fr/12.5Fr – 35,38,45,55 cms, 12Fr/14Fr – 35,38,45,55 cms and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon

23	Generic Name:Sclerotherapy Needle/ Varices Injector(VI) Model No.:NIL Intended Use:Used for endoscopic injection into gastrointestinal mucosa Class of medical device:Class B Material of construction:Stainless Steel, Medical Grade Polypropylene, Low density polyethylene Dimension(if any):21G-16,200,230 cm, 22G-16,200,230 cm, 23G-16,200,230 cm and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
24	Generic Name:TUR Set(TUR) Model No.:NIL Intended Use:TUR set used for Endoscopic irrigation during Trans Urethral Resection of prostate gland Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride Dimension(if any):22F-143 CM, 24F-143 CM and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
25	Generic Name:Infant Feeding Tube(IFT) Model No.:NIL Intended Use:Used for Neonatal or Pediatric nutrition delivery Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride Dimension(if any):5F-52 cm 6F-52 cm 7F-52 cm 8F-52 cm 9F-52 cm 10F-52 cm and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
26	Generic Name:Connecting Tube(CT) Model No.:NIL Intended Use:Used for connecting Catheters to the urine bag Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride Dimension(if any):14F-10,30 cm, 16F-10 cm, 18F-10cm, 24F-10 cm and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
27	Generic Name:Zulu Epidural Catheter/Set(ZEC) Model No.:NIL Intended Use:It is used for medical route of administration in which a drug or contrast agent is injected into the epidural space of the spinal cord Class of medical device:Class B Material of construction:Medical Grade Polyurethane Dimension(if any):3F-45 cm and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon

28	Generic Name:Embryo transfer catheter(ETC) Model No.:NIL Intended Use:Intended for use when cervical access is difficult Class of medical device:Class B Material of construction:Medical Grade Ethylene-vinyl acetate Dimension(if any):3F-27 cm and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
29	Generic Name:Fallopian tube Recanalisation Catheter(FTRC) Model No.:NIL Intended Use:Used for selective catheterization of the proximal fallopian tubes, Injection of contrast medium and evaluation of tubal patency Class of medical device:Class B Material of construction:Medical Grade Ethylene-vinyl acetate Dimension(if any):4/5F-40 cm and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
30	Generic Name:Abdominal Drainage Kit(ADK) Model No.:NIL Intended Use:Specially designed for post operative abdominal drainage Class of medical device:Class B Material of construction:Medical Grade Polyvinyl chloride Dimension(if any):18F-22 cm, 20F-22, 22F-22 cm, 24F-22 cm,28F-22 cm, 32F-22 cm and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
31	Generic Name:Feeding Tube(FT) Model No.:NIL Intended Use:Used to supply nutrition Class of medical device:Class B Material of construction:Medical Grade Ethylene-vinyl acetate Dimension(if any):10F/125 cm,12F/125 cm, 14F/125 cm,16F/125 cm and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon

32	Generic Name:Re-entry Malecot catheter(REMC) Model No.:NIL Intended Use:Used for internal as well as external drainage with combination of nephrostomy catheter with stent Class of medical device:Class B Material of construction:Medical Grade Ethylene-vinyl acetate Dimension(if any):10/5F-22/26 cm,24/26 cm ,26 /26 cm, 10/6F-22/26cm,24/26cm,26 /26cm, 12/6F- 22/26cm,24/26cm,26 /26cm,30/17cm, 14/6F-22/26cm,24/26cm, 26 /26cm, 30/17cm, 14/7F- 22/26cm,24/26cm, 26 /26cm,30/17cm, 16/7F-22/26cm,24/26cm, 26 /26cm,30/17cm, 16/8F- 22/26cm,24/26cm, 26 /26cm,30/17cm, 18/8F-22/26cm,24/26cm, 26 /26cm,30/17cm, 20/8F- 22/26cm,24/26cm, 26 /26cm,30/17cm and other Dimensions Shelflife:3 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon
33	Generic Name:Percutaneous Nephrolithotomy Set(PCNLS) Model No.:NIL Intended Use:These are convenience kits containing multiple devices to perform removal of stones in the kidney Class of medical device:Class B Material of construction:Medical Grade Ethylene-vinyl acetate+ Polypropylene Dimension(if any):8F-20,22 cm 10F-20,22 cm 12F-20,22 cm 14F-20,22 cm 16F-20,22 cm 18F-20,22 cm and other Dimensions Shelflife:5 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Devon

Place:

Date02-Mar-22

State Licensing Authority