



Post Approval

File No : MD/PostAppr/2023/19439

To

M/s NEDHI MEDITECH SYSTEMS, A-207, TIRTHRAJ COMPLEX,
OPP VS HOSPITAL, ELLISBRIDGE , AHMEDBAD - 380007
AHMEDABAD, Ahmedabad, Gujarat (India) - 380007 Telephone No.:
00-00000000 FAX: 00-00000000 Email: divyang1411@gmail.com

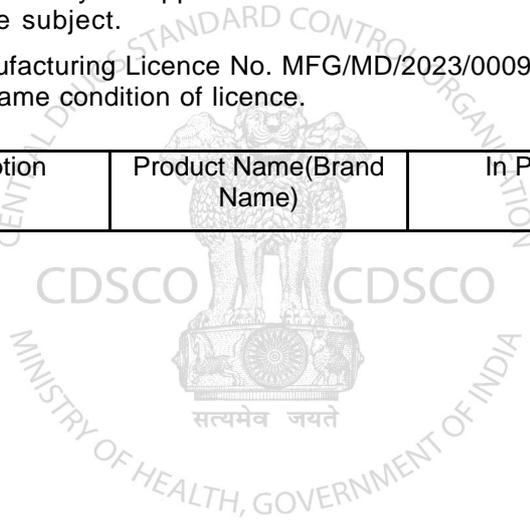
Sub: Post approval change in Manufacturing License No. MFG/MD/2023/000908 Dated 17/10/2023 .

Sir,

This is with reference to your application number MD/PostAppr/2023/19439 dated 30/10/2023 regarding the above subject.

The Change in Manufacturing Licence No. MFG/MD/2023/000908 as mentioned below is approved with subject to the same condition of licence.

Change Description	Product Name(Brand Name)	In Place of	To be Read as
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Digitally signed by Dr.
H.G.KOSHIA
DN: cn=Dr.
H.G.KOSHIA, o=Food
and Drugs Control
Administration,
ou=Commissioner,
email=comfdca@guja
rat.gov.in, c=IN
Date: 2023.10.30
16:30:15 +05'30'

Amendment/Correction/Others	<p>Intra Corporeal Pneumatic Lithotripter(Nidhi Lith Digi), Suction / Irrigation Pump(Nidhi Easy Plus Flow Pump), Cystoscope Sheaths with Obturator And Bridge (Nidhi), Resectoscope Sheaths(Nidhi), Intra Corporeal Pneumatic Lithotripter(Nidhi Lith Semi Digi), Uroflowmetry Systems(Nidhi Flow 814), Uroflowmetry Systems(Nidhi Flow 8130), Manual Blader Stone Fragmentation Punch Set(Nidhi), Resectoscope Working Element (Nidhi), All Types Of Stone Grasping Forceps From Kidney ureter and bladder (Nidhi), Optical Biopsy Forceps (Nidhi), DJ Stent Removal Forcep (Nidhi), Biopsy Forcep(Nidhi), Alken Telescopic Dilator Set(Nidhi), OTIS Urethrotome with 2 knives(Nidhi), Toomey Syringe (Nidhi), All Types Of Urethral Dialators (Nidhi)</p>	M/s NEDHI MEDITECH SYSTEMS , M/s NIDIH MEDITECH SYSTEMS	M/s NIDHI MEDITECH SYSTEMS FROM M/s NEDHI MEDITECH SYSTEMS , M/s NIDIH MEDITECH SYSTEMS
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Digitally signed by Dr. H.G.KOSHIA
 DN: cn=Dr. H.G.KOSHIA, o=Food and Drugs Control Administration, ou=Commissioner, email=comfdca@gujarat.gov.in, c=IN
 Date: 2023.10.30 16:29:59 +05'30'

LICENSING AUTHORITY

Government of India
 Directorate General of Health Services
 Central Drugs Standard Control Organisation
 Ministry of Health and Family welfare
 (Medical Device and Diagnostic Division)

FREE SALE CERTIFICATE

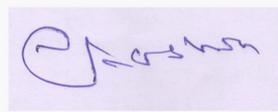
FSC Number : FSC/MD/2023/000566

Dated : 06/11/2023

This is to certify that M/s. NEDHI MEDITECH SYSTEMS ,NIDIH MEDITECH SYSTEM situated at address H 28,29,30 ABHISHEK ESTATE - 3, OPP HARIPURA BUS STOP, ASARWA, ,Ahmedabad Gujarat ,380016,00-00000000, India is holding Manufacturing License no. MFG/MD/2023/000908 issued on 17-OCT-2023 Under this license, the said firm is permitted to manufacture the products for their manufacture and sale in domestic market as per Indian Law and for export as per law of importing country (ies):-

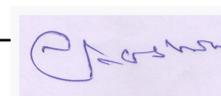
Name of the products with their product name and dimensions if any mentioned below :

S.NO	Medical Device Details
1	1. Generic Name :Intra Corporeal Pneumatic Lithotripter 2. Brand Name :Nidhi Lith Digi 3. Notified Category :OthersElectromechanical lithotripsy system, intracorporeal 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an intracorporeal Pneumatic Lithotripter being used for Stone fragmentation of Kidney, Bladder and Ureter through an endoscopic procedure. 8. Material of Construction: Rust Free Palstic 9. Dimension: L 195mm * W 240mm * H 125mm 10. Model/Catalogue No./Name :NIL
2	1. Generic Name :Intra Corporeal Pneumatic Lithotripter 2. Brand Name :Nidhi Lith Semi Digi 3. Notified Category :OthersElectromechanical lithotripsy system, intracorporeal 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an intracorporeal Pneumatic Lithotripter being used for Stone fragmentation of Kidney, Bladder and Ureter through an endoscopic procedure. 8. Material of Construction: Rust Free Palstic 9. Dimension: L 250mm * W 155mm * H 230mm 10. Model/Catalogue No./Name :NIL

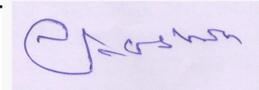


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 ou=Commissioner,
 email=comfdca@gujarat.gov.in,
 c=IN
 Date: 2023.11.06 19:02:38 +05'30'

3	<p>1. Generic Name :Uroflowmetry Systems 2. Brand Name :Nidhi Flow 814 3. Notified Category :OthersUrodynamic measurement system 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Uroflowmetry is a non invasive diagnostics system to dianose prostate, stricture and abnormality in Urinary track. It is used to measure the patinets urine flow rate 8. Material of Construction: Rust Free Palstic 9. Dimension: L 290mm * B 210mm * H 105mm 10. Model/Catalogue No./Name :NIL</p>
4	<p>1. Generic Name :Uroflowmetry Systems 2. Brand Name :Nidhi Flow 8130 3. Notified Category :OthersUrodynamic measurement system 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Uroflowmetry is a non invasive diagnostics system to dianose prostate, stricture and abnormality in Urinary track. It is used to measure the patinets urine flow rate 8. Material of Construction: Rust Free Palstic 9. Dimension: L 100mm * B 100mm * H 62mm 10. Model/Catalogue No./Name :NIL</p>
5	<p>1. Generic Name :Suction / Irrigation Pump 2. Brand Name :Nidhi Easy Plus Flow Pump 3. Notified Category :OthersIntracorporeal lithotripsy suction system 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is a device to use during the Urology, Endo Urology , Laproscopy, Arthroscopy and Gynec procedures for pressure control precise fluid irrigation and suction. 8. Material of Construction: Alluminium 9. Dimension: L 320mm * B 220mm * H 180mm 10. Model/Catalogue No./Name :NIL</p>
6	<p>1. Generic Name :Cystoscope Sheaths with Obturator And Bridge 2. Brand Name :Nidhi 3. Notified Category :OthersRigid cystourethroscope 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an accessory of Cystoscope. A hand-held manual surgical instrument designed for the diagnosis minor surgery in Urethra and Bladder. 8. Material of Construction: SS-304 9. Dimension: NA 10. Model/Catalogue No./Name :NIL</p>
7	<p>1. Generic Name :Manual Blader Stone Fragmentation Punch Set 2. Brand Name :Nidhi 3. Notified Category :OthersLithotrite 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :To be used to fragment the bladder stone. 8. Material of Construction: SS-304 9. Dimension: NA 10. Model/Catalogue No./Name :NIL</p>
8	<p>1. Generic Name :Resectoscope Sheaths 2. Brand Name :Nidhi 3. Notified Category :OthersRigid cystourethroscope 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an accessory of Resectoscope to be used in Bladder urethra for various TUR-P surgeries. 8. Material of Construction: SS-304 9. Dimension: NA 10. Model/Catalogue No./Name :NIL</p>



9	<ol style="list-style-type: none"> 1. Generic Name :Resectoscope Working Element 2. Brand Name :Nidhi 3. Notified Category :OthersRigid Cystourethro Scope 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an accessory of Resectoscope to be used in Bladder urethra for various TUR-P surgeries. 8. Material of Construction: SS-304 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
10	<ol style="list-style-type: none"> 1. Generic Name :All Types Of Stone Grasping Forceps From Kidney ureter and bladder 2. Brand Name :Nidhi 3. Notified Category :OthersUrology 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an accessory to be used to remove the stone from Ureter kidney bladder 8. Material of Construction: Stainless Steel 9. Dimension: URS OD 1.0mm 1.3mm 1.7mm * L 610mm PCNL OD 2.0mm 3.0 mm 4.0mm * L 360mm Mini PCNL OD 1.0mm 1.3mm 1.7mm * L450mm 10. Model/Catalogue No./Name :NIL
11	<ol style="list-style-type: none"> 1. Generic Name :Optical Biopsy Forceps 2. Brand Name :Nidhi 3. Notified Category :OthersUrology 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an accessory to extract the Biopsy Tissue during TURP optical procedures. 8. Material of Construction: Stainless Steel and Brass 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
12	<ol style="list-style-type: none"> 1. Generic Name :DJ Stent Removal Forcep 2. Brand Name :Nidhi 3. Notified Category :OthersUrology 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Flexible Forceps to remove the stents. 8. Material of Construction: Stainless Steel and Brass 9. Dimension: OD 1.8mm * L 520mm 10. Model/Catalogue No./Name :NIL
13	<ol style="list-style-type: none"> 1. Generic Name :Biopsy Forcep 2. Brand Name :Nidhi 3. Notified Category :OthersUrology 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Flexible Forceps to extract the Biopsy Tissue. 8. Material of Construction: Stainless Steel and Brass 9. Dimension: OD 1.8mm * L 520mm 10. Model/Catalogue No./Name :NIL
14	<ol style="list-style-type: none"> 1. Generic Name :Alken Telescopic Dilator Set 2. Brand Name :Nidhi 3. Notified Category :OthersUrology 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an accessory of Rigid Nephroscope to use for the dilator for the nephroscope during PCNL surgeries. 8. Material of Construction: SS-304 9. Dimension: 8 fr - 30 fr 10. Model/Catalogue No./Name :NIL



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DN: cn=Dr. H.G.KOSHIA, o=Food
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c=IN
Date: 2023.11.06 19:02:19 +05'30'

15	<ol style="list-style-type: none"> 1. Generic Name :OTIS Urethrotome with 2 knives 2. Brand Name :Nidhi 3. Notified Category :OthersRigid cystourethroscope 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :To be used to Dilate the Urethra 8. Material of Construction: SS-304 9. Dimension: L 295mm , knives L 130.2mm 10. Model/Catalogue No./Name :NIL
16	<ol style="list-style-type: none"> 1. Generic Name :Toomey Syringe 2. Brand Name :Nidhi 3. Notified Category :OthersRigid cystourethroscope 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Accessory to be used in Urology applications. 8. Material of Construction: Glass And SS 9. Dimension: 50 ml , 100 ml 10. Model/Catalogue No./Name :NIL
17	<ol style="list-style-type: none"> 1. Generic Name :All Types Of Urethral Dialators 2. Brand Name :Nidhi 3. Notified Category :OthersRigid cystourethroscope 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Accessory to be used in Urology surgeries for Dilation urethra 8. Material of Construction: Stainless Steel 9. Dimension: NA 10. Model/Catalogue No./Name :NIL

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H.G.KOSHIA
DN: cn=Dr. H.G.KOSHIA,
o=Food and Drugs Control
Administration,
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email=comfdca@gujarat.gov.in,
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Date: 2023.11.06 19:02:08
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Competent Authority

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
Ministry of Health and Family welfare
(Medical Device and Diagnostic Division)

FREE SALE CERTIFICATE

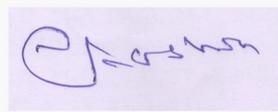
FSC Number : FSC/MD/2023/000566

Dated : 06/11/2023

This is to certify that M/s. NEDHI MEDITECH SYSTEMS ,NIDIH MEDITECH SYSTEM situated at address H 28,29,30 ABHISHEK ESTATE - 3, OPP HARIPURA BUS STOP, ASARWA, ,Ahmedabad Gujarat ,380016,00-00000000, India is holding Manufacturing License no. MFG/MD/2023/000908 issued on 17-OCT-2023 Under this license, the said firm is permitted to manufacture the products for their manufacture and sale in domestic market as per Indian Law and for export as per law of importing country (ies):-

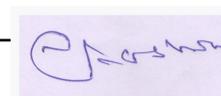
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S.NO	Medical Device Details
1	1. Generic Name :Intra Corporeal Pneumatic Lithotripter 2. Brand Name :Nidhi Lith Digi 3. Notified Category :OthersElectromechanical lithotripsy system, intracorporeal 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an intracorporeal Pneumatic Lithotripter being used for Stone fragmentation of Kidney, Bladder and Ureter through an endoscopic procedure. 8. Material of Construction: Rust Free Palstic 9. Dimension: L 195mm * W 240mm * H 125mm 10. Model/Catalogue No./Name :NIL
2	1. Generic Name :Intra Corporeal Pneumatic Lithotripter 2. Brand Name :Nidhi Lith Semi Digi 3. Notified Category :OthersElectromechanical lithotripsy system, intracorporeal 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an intracorporeal Pneumatic Lithotripter being used for Stone fragmentation of Kidney, Bladder and Ureter through an endoscopic procedure. 8. Material of Construction: Rust Free Palstic 9. Dimension: L 250mm * W 155mm * H 230mm 10. Model/Catalogue No./Name :NIL

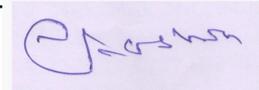


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 Date: 2023.11.06 19:02:38 +05'30'

3	<p>1. Generic Name :Uroflowmetry Systems 2. Brand Name :Nidhi Flow 814 3. Notified Category :OthersUrodynamic measurement system 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Uroflowmetry is a non invasive diagnostics system to dianose prostate, stricture and abnormality in Urinary track. It is used to measure the patinets urine flow rate 8. Material of Construction: Rust Free Palstic 9. Dimension: L 290mm * B 210mm * H 105mm 10. Model/Catalogue No./Name :NIL</p>
4	<p>1. Generic Name :Uroflowmetry Systems 2. Brand Name :Nidhi Flow 8130 3. Notified Category :OthersUrodynamic measurement system 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Uroflowmetry is a non invasive diagnostics system to dianose prostate, stricture and abnormality in Urinary track. It is used to measure the patinets urine flow rate 8. Material of Construction: Rust Free Palstic 9. Dimension: L 100mm * B 100mm * H 62mm 10. Model/Catalogue No./Name :NIL</p>
5	<p>1. Generic Name :Suction / Irrigation Pump 2. Brand Name :Nidhi Easy Plus Flow Pump 3. Notified Category :OthersIntracorporeal lithotripsy suction system 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is a device to use during the Urology, Endo Urology , Laproscopy, Arthroscopy and Gynec procedures for pressure control precise fluid irrigation and suction. 8. Material of Construction: Alluminium 9. Dimension: L 320mm * B 220mm * H 180mm 10. Model/Catalogue No./Name :NIL</p>
6	<p>1. Generic Name :Cystoscope Sheaths with Obturator And Bridge 2. Brand Name :Nidhi 3. Notified Category :OthersRigid cystourethroscope 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an accessory of Cystoscope. A hand-held manual surgical instrument designed for the diagnosis minor surgery in Urethra and Bladder. 8. Material of Construction: SS-304 9. Dimension: NA 10. Model/Catalogue No./Name :NIL</p>
7	<p>1. Generic Name :Manual Blader Stone Fragmentation Punch Set 2. Brand Name :Nidhi 3. Notified Category :OthersLithotrite 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :To be used to fragment the bladder stone. 8. Material of Construction: SS-304 9. Dimension: NA 10. Model/Catalogue No./Name :NIL</p>
8	<p>1. Generic Name :Resectoscope Sheaths 2. Brand Name :Nidhi 3. Notified Category :OthersRigid cystourethroscope 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an accessory of Resectoscope to be used in Bladder urethra for various TUR-P surgeries. 8. Material of Construction: SS-304 9. Dimension: NA 10. Model/Catalogue No./Name :NIL</p>



9	<p>1. Generic Name :Resectoscope Working Element 2. Brand Name :Nidhi 3. Notified Category :OthersRigid Cystourethro Scope 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an accessory of Resectoscope to be used in Bladder urethra for various TUR-P surgeries. 8. Material of Construction: SS-304 9. Dimension: NA 10. Model/Catalogue No./Name :NIL</p>
10	<p>1. Generic Name :All Types Of Stone Grasping Forceps From Kidney ureter and bladder 2. Brand Name :Nidhi 3. Notified Category :OthersUrology 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an accessory to be used to remove the stone from Ureter kidney bladder 8. Material of Construction: Stainless Steel 9. Dimension: URS OD 1.0mm 1.3mm 1.7mm * L 610mm PCNL OD 2.0mm 3.0 mm 4.0mm * L 360mm Mini PCNL OD 1.0mm 1.3mm 1.7mm * L450mm 10. Model/Catalogue No./Name :NIL</p>
11	<p>1. Generic Name :Optical Biopsy Forceps 2. Brand Name :Nidhi 3. Notified Category :OthersUrology 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an accessory to extract the Biopsy Tissue during TURP optical procedures. 8. Material of Construction: Stainless Steel and Brass 9. Dimension: NA 10. Model/Catalogue No./Name :NIL</p>
12	<p>1. Generic Name :DJ Stent Removal Forcep 2. Brand Name :Nidhi 3. Notified Category :OthersUrology 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Flexible Forceps to remove the stents. 8. Material of Construction: Stainless Steel and Brass 9. Dimension: OD 1.8mm * L 520mm 10. Model/Catalogue No./Name :NIL</p>
13	<p>1. Generic Name :Biopsy Forcep 2. Brand Name :Nidhi 3. Notified Category :OthersUrology 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Flexible Forceps to extract the Biopsy Tissue. 8. Material of Construction: Stainless Steel and Brass 9. Dimension: OD 1.8mm * L 520mm 10. Model/Catalogue No./Name :NIL</p>
14	<p>1. Generic Name :Alken Telescopic Dilator Set 2. Brand Name :Nidhi 3. Notified Category :OthersUrology 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :It is an accessory of Rigid Nephroscope to use for the dilator for the nephroscope during PCNL surgeries. 8. Material of Construction: SS-304 9. Dimension: 8 fr - 30 fr 10. Model/Catalogue No./Name :NIL</p>



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15	<ol style="list-style-type: none"> 1. Generic Name :OTIS Urethrotome with 2 knives 2. Brand Name :Nidhi 3. Notified Category :OthersRigid cystourethroscope 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :To be used to Dilate the Urethra 8. Material of Construction: SS-304 9. Dimension: L 295mm , knives L 130.2mm 10. Model/Catalogue No./Name :NIL
16	<ol style="list-style-type: none"> 1. Generic Name :Toomey Syringe 2. Brand Name :Nidhi 3. Notified Category :OthersRigid cystourethroscope 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Accessory to be used in Urology applications. 8. Material of Construction: Glass And SS 9. Dimension: 50 ml , 100 ml 10. Model/Catalogue No./Name :NIL
17	<ol style="list-style-type: none"> 1. Generic Name :All Types Of Urethral Dialators 2. Brand Name :Nidhi 3. Notified Category :OthersRigid cystourethroscope 4. Class of Medical Device :Class B 5. Shelf life :NIL 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Accessory to be used in Urology surgeries for Dilation urethra 8. Material of Construction: Stainless Steel 9. Dimension: NA 10. Model/Catalogue No./Name :NIL

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Competent Authority