



## 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

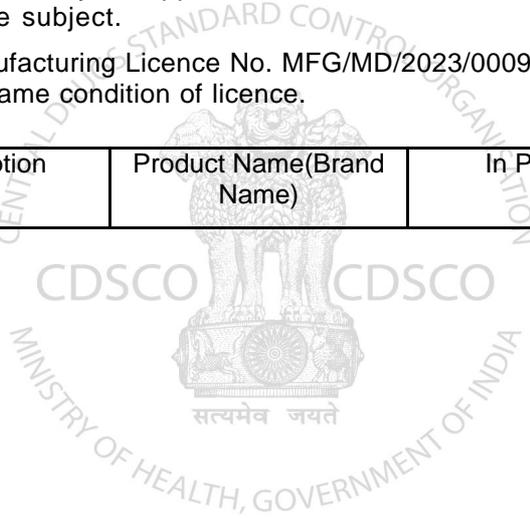
Sub: Post approval change in Manufacturing License No. MFG/MD/2023/000908 Dated 17/10/2023 .

Sir,

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

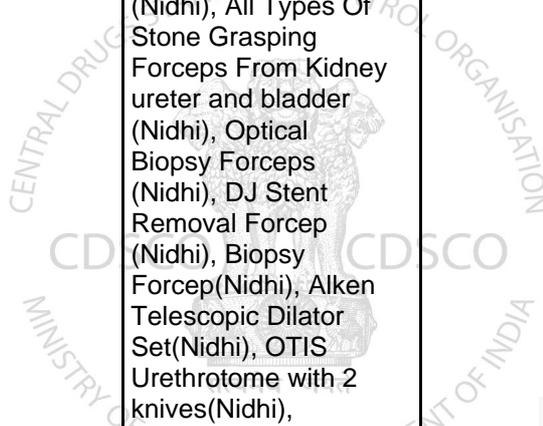
The Change in Manufacturing Licence No. MFG/MD/2023/000908 as mentioned below is approved with subject to the same condition of licence.

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



सत्यमेव जयते

## 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/2023/000908

1. M/s NEDHI MEDITECH SYSTEMS, A-207, TIRTHRAJ COMPLEX, OPP VS HOSPITAL, ELLISBRIDGE , AHMEDBAD - 380007AHMEDABAD, Ahmedabad, Gujarat (India) - 380007 Telephone No.: 00-00000000 FAX: 00-00000000 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s NIDIH MEDITECH SYSTEM, H 28,29,30 ABHISHEK ESTATE - 3, OPP HARIPURA BUS STOP, ASARWA, , Ahmedabad, Gujarat (India) - 380016 Telephone No.: 00-00000000 FAX: 00-00000000

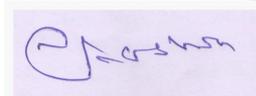
2. Details of medical device(s) [Annexed]

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:Intra Corporeal Pneumatic Lithotripter Model No.:NIL Intended Use:It is an intracorporeal Pneumatic Lithotripter being used for Stone fragmentation of Kidney, Bladder and Ureter through an endpsopic procedure. Class of medical device:Class B Material of construction:Rust Free Palstic Dimension(if any):L 195mm * W 240mm * H 125mm Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Nidhi Lith Digi
2	Generic Name:Intra Corporeal Pneumatic Lithotripter Model No.:NIL Intended Use:It is an intracorporeal Pneumatic Lithotripter being used for Stone fragmentation of Kidney, Bladder and Ureter through an endpsopic procedure. Class of medical device:Class B Material of construction:Rust Free Palstic Dimension(if any):L 250mm * W 155mm * H 230mm Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Nidhi Lith Semi Digi
3	Generic Name:Uroflowmetry Systems Model No.:NIL 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 Class of medical device:Class B Material of construction:Rust Free Palstic Dimension(if any):L 290mm * B 210mm * H 105mm Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Nidhi Flow 814

4	<p>Generic Name:Uroflowmetry Systems  Model No.:NIL  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  Class of medical device:Class B  Material of construction:Rust Free Palstic  Dimension(if any):L 100mm * B 100mm * H 62mm  Shelflife:NIL  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Nidhi Flow 8130</p>
5	<p>Generic Name:Suction / Irrigation Pump  Model No.:NIL  Intended Use:It is a device to use during the Urology, Endo Urology , Laproscopy, Arthoscopy and Gynec procedures for pressure control precise fluid irrigation and suction.  Class of medical device:Class B  Material of construction:Allumunium  Dimension(if any):L 320mm * B 220mm * H 180mm  Shelflife:NIL  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Nidhi Easy Plus Flow Pump</p>
6	<p>Generic Name:Cystoscope Sheaths with Obturator And Bridge  Model No.:NIL  Intended Use:It is an accessory of Cystoscope. A hand-held manual surgical instrument designed for the diagnosis minor surgery in Urethra and Bladder.  Class of medical device:Class B  Material of construction:SS-304  Dimension(if any):  Shelflife:NIL  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Nidhi</p>
7	<p>Generic Name:Manual Blader Stone Fragmentation Punch Set  Model No.:NIL  Intended Use:To be used to fragment the bladder stone.  Class of medical device:Class B  Material of construction:SS-304  Dimension(if any):  Shelflife:NIL  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Nidhi</p>
8	<p>Generic Name:Resectoseope Sheaths  Model No.:NIL  Intended Use:It is an accessory of Resectoscope to be used in Bladder urethra for various TUR-P surgeries.  Class of medical device:Class B  Material of construction:SS-304  Dimension(if any):  Shelflife:NIL  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Nidhi</p>
9	<p>Generic Name:Resectoseope Working Element  Model No.:NIL  Intended Use:It is an accessory of Resectoscope to be used in Bladder urethra for various TUR-P surgeries.  Class of medical device:Class B  Material of construction:SS-304  Dimension(if any):  Shelflife:NIL  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Nidhi</p>



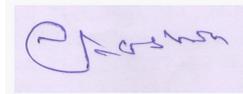
10	<p>Generic Name:All Types Of Stone Grasping Forceps From Kidney ureter and bladder  Model No.:NIL  Intended Use:It is an accessory to be used to remove the stone from Ureter kidney bladder  Class of medical device:Class B  Material of construction:Stainless Steel  Dimension(if any):URS OD 1.0mm 1.3mm 1.7mm * L 610mm PCNL OD 2.0mm 3.0mm 4.0mm * L 360mm Mini PCNL OD 1.0mm 1.3mm 1.7mm * L450mm  Shelflife:NIL  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Nidhi</p>
11	<p>Generic Name:Optical Biopsy Forceps  Model No.:NIL  Intended Use:It is an accessory to extract the Biopsy Tissue during TURP optical procedures.  Class of medical device:Class B  Material of construction:Stainless Steel and Brass  Dimension(if any):  Shelflife:NIL  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Nidhi</p>
12	<p>Generic Name:DJ Stent Removal Forcep  Model No.:NIL  Intended Use:Flexible Forceps to remove the stents.  Class of medical device:Class B  Material of construction:Stainless Steel and Brass  Dimension(if any):OD 1.8mm * L 520mm  Shelflife:NIL  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Nidhi</p>
13	<p>Generic Name:Biopsy Forcep  Model No.:NIL  Intended Use:Flexible Forceps to extract the Biopsy Tissue.  Class of medical device:Class B  Material of construction:Stainless Steel and Brass  Dimension(if any):OD 1.8mm * L 520mm  Shelflife:NIL  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Nidhi</p>
14	<p>Generic Name:Alken Telescopic Dilator Set  Model No.:NIL  Intended Use:It is an accessory of Rigid Nephroscope to use for the dilator for the nephroscope during PCNL surgeries.  Class of medical device:Class B  Material of construction:SS-304  Dimension(if any):8 fr - 30 fr  Shelflife:NIL  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Nidhi</p>
15	<p>Generic Name:OTIS Urethrotome with 2 knives  Model No.:NIL  Intended Use:To be used to Dilate the Urethra  Class of medical device:Class B  Material of construction:SS-304  Dimension(if any):L 295mm , knives L 130.2mm  Shelflife:NIL  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Nidhi</p>

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DN: cn=Dr. H.G.KOSHIA, o=Food and Drugs Control Administration, ou=Commissioner, email=comfdca@gujarat.gov.in, c=IN  
Date: 2023.10.17 17:41:13 +05'30'

16	<p>Generic Name:Toomey Syringe  Model No.:NIL  Intended Use:Accessory to be used in Urology applications.  Class of medical device:Class B  Material of construction:Glass And SS  Dimension(if any):50 ml , 100 ml  Shelflife:NIL  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Nidhi</p>
17	<p>Generic Name:All Types Of Urethral Dialators  Model No.:NIL  Intended Use:Accessory to be used in Urology surgeries for Dilation urethra  Class of medical device:Class B  Material of construction:Stainless Steel  Dimension(if any):  Shelflife:NIL  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Nidhi</p>

Place: GANDHINAGAR

Date:17-Oct-23



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and Drugs Control Administration,  
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Date: 2023.10.17 17:41:05 +05'30'

State Licensing Authority





सत्यमेव जयते

## 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/2023/000908

1. M/s NEDHI MEDITECH SYSTEMS, A-207, TIRTHRAJ COMPLEX, OPP VS HOSPITAL, ELLISBRIDGE , AHMEDBAD - 380007AHMEDABAD, Ahmedabad, Gujarat (India) - 380007 Telephone No.: 00-00000000 FAX: 00-00000000 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s NIDIH MEDITECH SYSTEM, H 28,29,30 ABHISHEK ESTATE - 3, OPP HARIPURA BUS STOP, ASARWA, , Ahmedabad, Gujarat (India) - 380016 Telephone No.: 00-00000000 FAX: 00-00000000

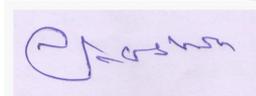
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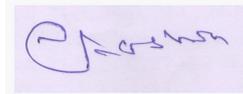
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Place: GANDHINAGAR

Date:17-Oct-23



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State Licensing Authority

