



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/2024/000084

1. M/s HIGHNESS MICROELECTRONICS PRIVATE LIMITED, Office 1C3, 1st Floor, Gundecha Onclave,, Kherani Road, Saki Vihar, Andheri (East) Mumbai Andheri, Mumbai City, Maharashtra (India) - 400072 Telephone No.: 9619797252 FAX: 9619797252 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Highness Microelectronics Private Limited, R-364, TTC Industrial Area, Rabale, Thane, Maharashtra (India) - 400701 Telephone No.: 022-28507123 FAX: 022 4026 4263

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	<p>Generic Name:2K Monitors Model No.:MHSD-1812 V1 - 463.50 x 287 x 51.5 mm,MHSD-1812 V2 - 463.50 x 287 x 51.5 mm, MHSD-2112 V1 - 515.70 x 312.30 x 52.11 mm,MHSD-2112 V2 - 515.70 x 312.30 x 52.11 mm, MHSD-2126 - 515.70 x 312.30 x 52.11 mm,MHSD-2412N V1 - 568.04 x 342.48 x 49.65 mm, MHSD-2412N V2 - 568.04 x 342.48 x 49.65 mm,MHSD-2426N - 568.04 x 342.48 x 49.65 mm,MHSD-2420N - 568.04 x 342.48 x 49.65 mm,MHSD-2712 V1 - 649.48 x 387.91 x 66.51 mm,MHSD-2712 V2 - 649.48 x 387.91 x 66.51 mm,MHSD-2720 - 649.48 x 387.91 x 66.51 mm, MHSD-3212 V1 - 745 X 434.90 X 62.38 mm,MHSD-3212 V2 - 745 X 434.90 X 62.38 mm, MHSD-3220 - 745 X 434.90 X 62.38 mm,MHSD-4312 V1 - 993.90 x 582.30 x 62.20 mm, MHSD-4312 V2 - 993.90 x 582.30 x 62.20 mm,MHSD-4320 - 993.90 x 582.30 x 62.20 mm, MHSD-5512 V1 - 1278.40 x 752.40 x 65.90 mm,MHSD-5512 V2 - 1278.40 x 752.40 x 65.90 mm,MHSD-5520 - 1278.40 x 752.40 x 65.90 mm</p> <p>Intended Use:Surgical Display, Laparoscopic, Uroendoscopy, Ophthal Imaging, Upper GI Endoscopy</p> <p>Class of medical device:Class B</p> <p>Material of construction:Metal(M.S.) Aluminium, LED Panel, Controller Board, Connecting Cables, Power Supply, Touch Screen / Toughened Glass.</p> <p>Dimension(if any):Mention in Model Details for respective products</p> <p>Shelflife:3 years</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Highness</p>

2	<p>Generic Name:4K Monitors  Model No.:MHSD-2740 - 649.64 x 385.76 x 62.01 mm ,MHSD-3240 - 790 x 490 x 62.51 mm ,  MHSD-4340 - 994.58 x 581.80 x 59.30 mm ,MHSD-5540 - 1282.50 x 754.40 x 101.90 mm  Intended Use:Surgical Display, Laparoscopy, GI Endoscopy, Bronchoscopy, Surgical  Microscopy, Arthroscopy, Neurospine Surgery, Digital OR  Class of medical device:Class B  Material of construction:Metal(M.S.) Aluminium, LED Panel, Controller Board, Connecting  Cables, Power Supply, Touch Screen / Toughened Glass  Dimension(if any):Mention in Model Details for respective products  Shelflife:3 years  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Highness</p>
3	<p>Generic Name:Surgical Display built in recorder  Model No.:MHSD-2100RCT - 521.80 x 318.30 x 64.10 mm,MHSD-2400NRCT - 568.04 x  342.48 x 63.00 mm,MHSD-2700RCT - 649.48 x 387.91 x 76.80 mm,MHSD-3200RCT - 745 X  434.90 X 64.50 mm,MHSD-4300RCT - 993.90 x 582.30 x 69.50 mm,MHSD-5500RCT -  1278.40 x 752.40 x 75.75 mm  Intended Use:Surgical Display, Laparoscopy, GI Endoscopy, Bronchoscopy, Surgical  Microscopy, Arthroscopy, Neurospine Surgery, Digital OR, Anaesthesia Workstation, EEG  Class of medical device:Class B  Material of construction:Metal(M.S.) Aluminium, LED Panel, Controller Board, Connecting  Cables, Power Supply, Touch Screen / Toughened Glass.  Dimension(if any):Mention in Model Details for respective products  Shelflife:3 years  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Highness</p>
4	<p>Generic Name:Surgical Display built in computer / Medical work station  Model No.:MHSD-1800WST - 447.80 x 278.40 x 65.90 mm,MHSD-2100WST - 521.80 x 318.30  x 60.31 mm,MHSD-2400WST - 568.04 x 342.48 x 63 mm,MHSD-2700WST - 649.48 x 387.91 x  76.80 mm,MHSD-3200WST - 745 X 434.90 X 64.50 mm  Intended Use:Surgical Display, Laparoscopy, GI Endoscopy, Bronchoscopy, Surgical  Microscopy, Arthroscopy, Neurospine Surgery, Digital OR, PACS / HIS  Class of medical device:Class B  Material of construction:Metal(M.S.) Aluminium, LED Panel, Controller Board, Connecting  Cables, Power Supply, Touch Screen / Toughened Glass  Dimension(if any):Mention in Model Details for respective products  Shelflife:3 years  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Highness</p>

Place:

Date:13-Feb-24

State Licensing Authority