



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/2023/000002

1. M/s Plasti Surge Industries Pvt Ltd, A70, MIDC Industrial Area Amravati, Amravati, Maharashtra (India) - 444607 Telephone No.: 9923332321 FAX: 721-2520505 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Plasti Surge Industries Pvt Ltd, A70, MIDC Industrial area, Amravati, Maharashtra (India) - 444607 Telephone No.: 9923332321 FAX: 721-2520505

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:Electrocardiograph Model No.:NIL Intended Use:An electrocardiograph is a device used to process the electrical signal transmitted through two or, more electrocardiograph electrodes and to produce a visual display of the electrical signal produced by the heart Class of medical device:Class B Material of construction:electronics Dimension(if any):Length: 10 to 15cm, width: 5 to 10 cm Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):PSI</p>
2	<p>Generic Name:Sterilization Wraps Model No.:PSI-412/A - Wrapping Sheet - SMMS -100 x 100 cm,PSI-412/B - Wrapping Sheet - SMMS-120 x 120 cm,PSI-412/C - Wrapping Sheet - SMMS-40 x 40 cm,PSI-412/D - Wrapping Sheet - SMMS-50 x 50 cm,PSI-412/E - Wrapping Sheet - SMMS-60 x 60 cm,PSI-412/F - Wrapping Sheet - SMMS -75 x 75 cm,PSI-412/G - Wrapping Sheet - SMMS-90 x 90 cm,PSI-413 - Split Sheet - SMMS - 150x200cm Intended Use:It is intended to allow sterilization of the enclosed medical, device and also to maintain sterility of the enclosed device, until used Class of medical device:Class B Material of construction:Nonwoven SMS/SMMS/SMMMS Dimension(if any):"Length: 20 cm to 160cm Width: 20 cm to 160cm" Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):PSI</p>