

## 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/2022/000590

- 1. M/s Plasti Surge Industries Pvt Ltd, A70, MIDC Industrial AreaAmravati, 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     | Generic Name:Umbilical cord clamp  |
|       | Model No.:PSI-110 - D.G.UMBILICAL CORD CLAMP   |
|       | Intended Use:An umbilical cord clamp is a clip, tie, tape, or other, article used to |
|       | close the blood vessels in the umbilical cord, of a newborn infant                   |
|       | Class of medical device:Class A  |
|       | Material of construction:HDPE plastic  |
|       | Dimension(if any):5 to 8 cm  |
|       | Shelflife:3 years  |
|       | Sterile or Non sterile:Sterilized  |
|       | Brand Name(if registered under the Trade Marks Act, 1999):PSI                        |
| 2     | Generic Name:Non-latex Medical examination gloves                                    |
| 2     | Model No.:PSI-115 - UNSTERILISED GLOVES FREE SIZE ( Without Paper cover ) ,PSI-      |
|       | 115/A - STERILISED GLOVES SMALL/MEDIUM/LARGE (With Paper Cover) ,PSI-215 -           |
|       | VETERINARY GLOVES A.I. Gloves / Full Arm Gloves                                      |
|       | Intended Use:Gloves made of synthetic materials, and used to protect the, patient    |
|       | and users from cross infection during examination,, check-up, treatment and          |
|       | handling of contaminated medical, materials except for surgery.                      |
|       | Class of medical device:Class A  |
|       | Material of construction:Polyethylene plastic  |
|       | Dimension(if any):25cm to 40 cm  |
|       | Shelflife:NIL  |
|       | Sterile or Non sterile:Non-Sterilized  |
|       | Brand Name(if registered under the Trade Marks Act, 1999):PSI                        |