1. PRODUCT DESCRIPTION:

The umbilical cord is made of plastic which closes when two open ends are pressed. It is available in two variants as openable and non-openable

Duration of Use: Short term use.
Material of composition: PP.

2. DEVICE CLASSIFICATION AND RULE:

The device is classified as Class Is/Rule1, medical device (classification as per MDR Annex II Section 1.1(f); Annex VIII.)

3. INTENDED USE:

Umbilical cord clamp intended use is to clamp over the new born infants umbilical cord at delivery and prevent blood loss as the cord dries and shrinks after birth.

4. PRODUCT VARIANTS:

Following variants are available for the products:

S.NO	Product	Size	GMDN Code	Classification / Rule	Sterilized
1.	Umbilical cord clamp	Universal size	43998	Class-Is, Rule-1	EO (Ethylene Oxide)

5. MATERIAL OF CONSTRUCTION:

S.No	Component Description	Material used
1	Umbilical Cord Clamp	Polypropylene

6. PRODUCT SPECIFICATION:

- Equipped with a T-shaped male and female interlocking closure system that can be easily operated with one hand and provides an audible/perceptible locking indication.
- Ensures irreversible closure and cannot be reopened once locked.
- Manufactured with a uniform and high-quality finish, featuring a completely smooth external surface, rounded atraumatic edges, and no irregularities.
- Free from any guillotine, razor, blade, or other sharp cutting mechanism, ensuring safety for both newborns and healthcare personnel.
- The internal surface of the jaws is designed with continuous grooving and atraumatic saw-like serrations to provide effective grip without causing tissue damage.
- Ensures perfect fitting between the jaws, is non-slippery, and remains securely in position after application.
- Manufactured from lightweight material that does not pull or allow the umbilical cord to fall.
- Available in white or beige colour.
- Dimensions are as follows:

  -Length: 6 cm ± 1 cm

-Width: 1 cm ± 0.5 cm

- Designed as a ligature/vascular clamp type medical device specifically intended for occlusion of the newborn umbilical cord immediately after birth, preventing hemorrhage and ensuring atraumatic closure without cutting the cord.
- The closure system provides airtight occlusion of the umbilical vessels without severing the umbilical cord.
- Manufactured from Medical Grade Polypropylene (PP).

7. REFERENCE COMPLIANCE STANDARD:

S.No.	Name Of Standard	Standards
1.	Medical devices-Quality management systems-Requirements for regulatory purposes.	EN ISO 13485:2016
2.	Medical devices-application of risk management to medical devices.	EN ISO 14971:2019
3.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	EN ISO 15223-1:2021
4.	Sampling Procedure For Inspection By attributes	ISO 2859-1:2026
5.	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of sterilization process for medical devices.	EN ISO 11135:2014/ A1:2019
6.	Sterilization of health care products - Biological indicators - Part 1: General requirements.	EN ISO 11138-1:2017
7.	Sterilization of health care products-Microbiological methods - Part 1: Determination of a population of microorganism on products.	EN ISO 11737-1:2018/ A1:2021
8.	Biological evaluation of medical devices - part 1, Evaluation and testing within a risk management process.	EN ISO 10993-1:2025
9.	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.	EN ISO 10993-3:2014
10.	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood.	EN ISO 10993-4:2017
11.	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.	EN ISO 10993-5:2009/ A11:2025
12.	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.	EN ISO 10993-7:2008/ A1:2022
13.	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.	EN ISO 10993-11:2018
14.	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.	EN ISO 10993-12:2021

15.	Biological evaluation of medical devices-Part 17: Establishment of allowable limits for leachable substances.	EN ISO 10993-17:2023
16.	European council directive concerning medical devices.	MDD 93/42/EEC , 2007/47/EC
17.	Surgical instruments — Materials Part 1: Metals	ISO 7153-1:2016
18.	Instruments for surgery — Scissors and shears — General requirements and test methods	ISO 7741:1986

8. PACKAGING DETAILS:

Packaging specifications		
1.	Individual pack	01 Nos.
2.	Inner Box	50 Nos.
3.	Outer / Master Carton	500 Nos.

9. OTHER DETAILS

Storage: store in a cool and dry place and keep away from direct sunlight and extreme heat.

Method of Sterilization: sterilized using ethylene oxide.

Shelf life: 05 years from the month / date of sterilization.

Biocompatibility: the product is tested as per the international standard ISO 10993-1 and parts applicable, and evaluation results are found conform to the standard requirements. The report from the actual study is available with Quality Assurance and will be available for review on request.

Disposal: Dispose of the used product in to biohazard container / clinical wastage bag or according to hospital and country specific protocol.

10.COMPLIANCE INFORMATION:

Manufacturer Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2, Phase-II, Sec-59, Ballabgarh, Faridabad-121004, Haryana (INDIA)
Drug Manufacturing License No.: MFG/MD/2019/000106
QMS Certification: EN ISO 13485:2016, TUV SUD Product Service GmbH
CE Marking: TUV SUD Product Service: GmbH, EC Notified body No. 0123
GMDN Code: 43998

11. ABBREVIATIONS:

QMS – Quality Management System
GMDN – Global Medical Device Nomenclature