



Sterimed Medical Devices Pvt. Ltd.



EN ISO 13485:2016



0123

MFRS. OF: MEDICAL DISPOSABLES,
CIN NO.: U33119DL2003PTC119500

DOC. No.: SMD/2022/CE-03/01

EC DECLARATION OF CONFORMITY

Manufacturer:-

Name : **Sterimed Group**

Address: 501, Ring Road Mall, 21, Manglam Place, Rohini, Sec-3, Delhi - 110085 (INDIA)

Unit-I : Sterimed Medical Devices Pvt. Ltd.

Address : Plot No.-211A, Sector -16, HSIIDC, Bahadurgarh, Jhajjar, Haryana 124507 (India)

Tel : 00 91 11 48880000 Fax: 00 91 11 45402277

European Representative:

Name & Address: OBELIS S.A. Bd, General Wahis, 53, 1030, Brussels, Belgium, Email:mail@obelis.net

1. Product Name: Endotracheal Tube

The GMDN Code: 46967

Classification and Relevant Rule of MDD: IIa, MDD 93/42/EEC Annex IX, Rule 5

Product Variants: Endotracheal Tube (Endotracheal Tube (Plain/Cuffed), ET Tube Reinforced (Plain/Cuffed), ET Tube Preformed North Nasal (Plain/Cuffed), ET Tube Preformed South Oral (Plain/Cuffed), ET Tube Preformed Pearl Nasal, ET Tube with Subglottic Suction.

Types/ Sizes: (I.D. in mm) 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 10.0

2. Product Name: Suction Catheter

The GMDN Code: 34923

Classification and Relevant Rule of MDD: IIa, MDD 93/42/EEC Annex IX, Rule 5

Product Variants: Suction Catheter (Suction Catheter with Thumb Control, Suction Catheter with Finger Tip Control, Suction Catheter with Atraumatic Tip, Closed Suction Catheter System).

Types/ Sizes: (O.D. in mm) 1.70(05 FG), 2.00(06 FG), 2.70(08 FG), 3.30(10 FG), 4.00(12 FG), 4.70(14 FG), 5.30 (16 FG), 6.00 (18FG), 6.70(20 FG)

3. Product Name: Tracheostomy Tube

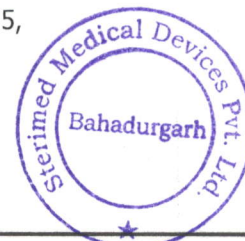
The GMDN Code: 35404

Classification and Relevant Rule of MDD: IIa MDD 93/42/EEC Annex IX, Rule 7

Product Variants: Tracheostomy Tube (Tracheostomy Tube Plain/Cuffed with and without Inner Cannula, Tracheostomy Tube with speaking valve).

Types/ Sizes: (I.D. in mm) 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,

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Regd. Office : 501, Ring Mall, Manglam Place, Sec-3, Rohini New Delhi-110085 (India)

Tel. : +91-011-42466196 / 42466396 / 48880000 Fax : +91-11-2522-0907

Website : www.sterimedgroup.com, Email:info@sterimedgroup.com

Works: Plot No. 211A, Sector-16, HSIIDC, Bahadurgarh, Jhajjar, Haryana - 124507 (INDIA)



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4. Product Name: Guedel Airways

The GMDN Code: 42424

Classification and Relevant Rule of MDD: IIa MDD 93/42/EEC Annex IX, Rule 5

Product Variants: Guedel Airways (Oropharyngeal Airway)

Types/ Sizes:(In No.) 000, 00, 0, 1, 2, 3, 4, 5, 6

5. Product Name: Nasogastric Tube

The GMDN Code: 14221

Classification and Relevant Rule of MDD: IIa MDD 93/42/EEC Annex IX, Rule 5

Product Variants: **Nasogastric Tube** (Salem sump Tube/ Ryle`s Tube/ Levin`s Tube, Feeding Tube)

Types/ Sizes:

Salem sump Tube:(O.D. in mm) 3.30(10 FG), 4.00(12 FG), 4.70(14 FG), 5.30 (16 FG), 6.00 (18FG), 6.70(20 FG)

Ryle`s Tube:(O.D. in mm) 2.00(06 FG), 2.70(08 FG), 3.30(10 FG), 4.00(12 FG), 4.70(14 FG), 5.30 (16 FG), 6.00 (18FG), 6.70(20 FG)

Levin`s Tube:(O.D. in mm) 2.00(06 FG), 2.70(08 FG), 3.30(10 FG), 4.00(12 FG), 4.70(14 FG), 5.30 (16 FG), 6.00 (18FG), 6.70(20 FG)

Feeding Tube: (O.D. in mm) 1.34(04 FG), 1.67(05 FG), 2.00(06 FG), 2.70(08 FG), 3.30(10 FG), 4.00(12 FG)

6. Product Name: Karman Cannula

The GMDN Code: 32655

Classification and Relevant Rule of MDD: IIa MDD 93/42/EEC Annex IX, Rule 5

Product Variants: Not Applicable.

Types/ Sizes: (O.D. in mm) 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0, 12.0

7. Product Name: Foley Balloon Catheter

The GMDN Code: 34917

Classification and Relevant Rule of MDD: IIa MDD 93/42/EEC Annex IX, Rule 5

Product Variants: Foley Balloon Catheter 2 way/3 way (Silico Latex & All Silicon)

Types/ Sizes:

Foley Balloon Catheter 2 way: (O.D. in mm) 2.00 (06 FG), 2.70 (08 FG), 3.30 (10 FG), 4.00 (12 FG), 4.70 (14 FG), 5.30 (16 FG), 6.00 (18FG), 6.70(20 FG), 7.30(22 FG), 8.00(24 FG), 8.70(26 FG), 9.30(28 FG), 10.0(30 FG)

Foley Balloon Catheter 3 way: (O.D. in mm) 4.70 (14 FG), 5.30 (16 FG), 6.00 (18FG), 6.70(20 FG), 7.30(22 FG), 8.00(24 FG), 8.70(26 FG), 9.30(28 FG), 10.0(30 FG) For Foley Balloon Catheter 3 way

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8. Product Name: Thoracic Drainage Catheter

The GMDN Code: 11308

Classification and Relevant Rule of MDD: IIa MDD 93/42/EEC Annex IX, Rule 5

Product Variants: Not Applicable

Types/ Sizes: (O.D. in mm) 2.70 (08 FG), 3.30 (10 FG), 4.00 (12 FG), 4.70 (14 FG), 5.30 (16 FG), 6.00 (18FG), 6.70(20 FG), 7.30(22 FG), 8.00(24 FG), 8.70(26 FG), 9.30(28 FG), 10.0(30 FG), 10.70(32 FG), 11.30(34 FG), 12.00(36 FG)

9. Product Name: Drainage Catheter

The GMDN Code: 31082

Classification and Relevant Rule of MDD: IIa MDD 93/42/EEC Annex IX, Rule 7

Product Variants: Redon Drainage Catheter, Closed Wound Suction Set, Kehr`s T Tube.

Types/ Sizes:

Redon Drainage Catheter: (O.D. in mm) 2.70 (08 FG), 3.30 (10 FG), 4.00 (12 FG), 4.70 (14 FG), 5.30 (16 FG), 6.00 (18FG)

Closed Wound Suction Set: (O.D. in mm) 2.70 (08 FG), 3.30 (10 FG), 4.00 (12 FG), 4.70 (14 FG), 5.30 (16 FG), 6.00 (18FG)

Kehr`s T Tube:(O.D. in mm) 4.00 (12 FG), 4.70 (14 FG), 5.30 (16 FG), 6.00 (18FG), 6.70(20 FG)

10. Product Name: Infant Mucus Extractor

The GMDN Code: 37773

Classification and Relevant Rule of MDD: Is MDD 93/42/EEC Annex IX, Rule 5

Product Variants: Not Applicable

Types/ Sizes: Not Applicable

We herewith declare that the above mentioned products meet the provision of the following EC Council Directives and Standards. All technical documentations are retained under the premises of the manufacturer.

DIRECTIVES

General Applicable Directives:

Medical Device Directive:

Council Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices (MDD 93/42/EEC)

Standard:

Harmonized Standards published in the official Journal of the European Communities applicable to product.

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CIN NO.: U33119DL2003PTC119500

Notified Body: TÜV SÜD product Service GmbH, Certification Body, Ridlerstraße65, 80339 Munich, Germany.

Identification Number: 0123

EC Certificate No.G2 103359 0006 Rev. 00, Valid From: 04-03-2021, Valid Until: 26-05-2024

Signature of Issue Person:

Position: Sr. Manager QC & QA

Name : Mr. Sukhbir Singh

Date: 25-04-2022

