





EC Certificate

Production Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in Class IIa, IIb or III)

No. G2 103359 0006 Rev. 00

Manufacturer:

Sterimed Group

Unit No-501, Ring Road Mall, 21 Manglam Place Rohini Sec 3 Delhi 110085

INDIA

Product Category(ies): Endotracheal Tube. Suction Catheter. Tracheostomy Tube. Guedel Airways. Nasogastric Tube. Karman Cannula. Foley Balloon Catheter Thoracic Drainage Catheter. Drainage Catheter. Infant Mucus Extractor. Product Variants:

- 1. 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).
- 2. Suction Catheter (Suction Catheter With Thumb Control, Suction Catheter with Finger Tip Control, Suction Catheter with Atraumatic Tip, Closed Suction Catheter System).
- 3. Tracheostomy Tube (Trachestomy Tube Plain /Cuffed With and without Inner Cannula, Tracheostomy Tube with speaking valve).
- 4. Guedel Airways (Oropharynegal Airway).
- 5. Nasogastric Tube (Salem Sump Tube/ Ryle's Tube/ Levin's Tube/Feeding Tube).
- 6. Foley Balloon Catheter 2-way/ 3-Way (Latex & All Silicon).
- 7. Drainage Catheter (Redon Drainage Catheter, Closed Wounf Suction Set, Kehr's T Tube).

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G2 103359 0006 Rev. 00

Report No.:

IND2020035_MDD

Valid from: Valid until: 2021-03-04 2024-05-26

Date,

Christoph Dicks

Head of Certification/Notified Body

SBIRENDRAS, SODHBANS Secretary General

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ATTESTED

2021-03-04

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Page 1 of 1 TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



भारत सरकार GOVERNMENT OF NOM अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1964)

Country

REPUBLIC OF INDIA

This public document

COMMERCIAL DOCUMENT

CONTINERCIAL DOCOME

has been signed by JASBIRENDRA'S SODHBANS

acting in the capacity of SECRETARY GENERAL

beers the seal/stemp of DELHI CHAMBER OF COMMERCE, NEW DELHI

Certified

at NEW DELHI, INDIA the 02-Jun-2021

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. DLND0013479721

Seal / Stamp

Signature

is issued to STERIMED MEDICAL DEVICES PVT.



(शुंभाव चनाप) (SUNIL CHANAP) अनुभाग अधिकारी (ओ.आई.) Section Officer (OI) श. क. के. प्रभाग / C.P.V Deviator विपेश अञ्चासम्म, गई विल्ली Ministry of External Affairs, New Dei 35006

No.

दिनांक Date

शींगिज्य मंडल में सहायक सचित्र उप सचित्र सम्बद्ध के हत्तावर सत्यापित किए जाते हैं।

The Signature of Assit. Secretary/Dy. Secretary/Secretary of Chamber of Commerce Altested.

विदेश मंत्रालय इस दस्तादेज के किसी 👈 विषय बस्तु की जिम्मेदारी नहीं लेता।

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