EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 2309178-1

Manufacturer: **Tianjin Medis Medical Device Co., Ltd.**
No.15-A, Saida One Avenue, Xiqing Economic Development Area,
300385 Tianjin, P.R. China

EUDAMED Single Registration No.: CN-MF-000020126

Products:

Products of class IIa:
R010301 - ENDOTRACHEAL TUBES, CUFFLESS
R010302 - ENDOTRACHEAL TUBES, CUFFED
R010501 - TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, UNCUFFED
R010502 - TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, CUFFED
R010401 - ENDOBRONCHIAL TUBES, RIGHT
R010402 - ENDOBRONCHIAL TUBES, LEFT
R010201 - LARYNGEAL MASKS

Products of class Is:
The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions:
R010101 - NASOPHARYNGEAL TUBES
R010380 - ENDOTRACHEAL TUBES - ACCESSORIES

Authorised representative(s): **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial revision	2022-11-21

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 190138199 120

Effective date: 2022-11-21

Expiry date: 2027-06-08

Issue date: 2022-11-21

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.