EC Declaration of Conformity

Manufacturer:

Name: Hangzhou Formed Medical Devices Co., Ltd.

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whose single Authorized Representative:

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SRN: DE-AR-000000001

Product name: **Intubating Stylet**
Trade name: Intubating Stylet
EMDN code: R018004 - INTUBATION DEVICE GUIDES.
Classification acc. to MDR Ax. VIII: Class I, rule 5
Conformity assessment procedure: Annex XI Part A of Medical Devices REGULATION (EU) 2017/745.
Basic UDI-DI: 69233109PA18019B acc. to GS1
Intended Use: The Intubating Stylet is designed to be inserted into the tracheal tube and pre-forming the tracheal tube to facilitate intubation, pull out the intubating stylet after intubation. Transient use.

We, the manufacturer, herewith declare that the products
Model:

PA180106, PA180108, PA180110, PA180112, PA180114, PA180206, PA180208, PA180110, PA180112, PA180114

under our sole responsibility meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

References to the relevant harmonized standards used, or references to the specifications in relation to which conformity is declared:

Regulation/Standard/Guidance	**Name of Document**
(EU) 2017/745	Medical Device Regulation
EP	European Pharmacopoeia
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
MDCG 2021-24	Guidance on classification of medical devices
EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
ISO/TR 24971:2020	Medical devices – Guidance on the application of ISO 14971
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
MDCG 2021-5	Guidance on standardization for medical devices
ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
ISO 639-1-2002	Codes for the representation of names of languages — Part 1: Alpha-2 code
ISO 22742:2010	Packaging — Linear bar code and two-dimensional symbols for product packaging

Regulation/Standard/Guidance	Name of Document
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)
EN ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
EN ISO 10993-23:2021	Biological evaluation of medical devices -- Part 23: Tests for irritation
ASTM F 1980-2021	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F88/F88M-15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1886/F1886M-16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
EN ISO 14698-2:2003+AC:2006	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN 62366-1:2015	Medical devices Part 1: Application of usability engineering to medical devices
IEC TR 62366-2	Medical devices – Part 2: Guidance on the application of usability engineering to medical devices
EN ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)
EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
MEDDEV. 2.7.1 Rev.4	Clinical evaluation: A guide for manufacturers and notified bodies
MEDDEV 2.12/2 Rev2	Post Market Clinical Follow-Up Studies A Guide for Manufacturers and Notified Bodies
MDCG 2020-13	Clinical evaluation assessment report template
MDCG 2020-8	Guidance on PMCF evaluation report template
MDCG 2020-7	Guidance on PMCF plan template

Regulation/Standard/Guidance	Name of Document
MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
MDCG 2019-9	Summary of safety and clinical performance A guide for manufacturers and notified bodies
PD CEN ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers

The medical device has been assigned to class **I** according to Rule 5 of Annex VIII of the Regulation (EU) 2017/745. It bears the mark:

CE 0123

Compliance of the designated product with the Regulation (EU) 2017/745 has been assessed and certified by the Notified Body

TÜV SÜD Product Service GmbH

Ridlerstraße 65, 80339 München, Germany

Certificate No.: G21 079078 0016 Rev. 00

Valid from: 2023-07-18

Valid until: 2028-07-17

Following the procedure relating to the EC Declaration of Conformity set out in Annex IV of Regulation (EU) 2017/745.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

All technical documents were retained under the promise of manufacturer.

Hangzhou, Jul. 08, 2024

Place, date

Signature: Guo Yongxuan, Function: General manager