document number：CE-SB02-02（A/0）

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:	Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao Mansion, No.5 Wen Er West Road, Xihu District, 310012 Hangzhou City, PEOPLE'S REPUBLIC OF CHINA
Trademark:	NA
SRN:	CN-MF-000016032
EuropeanRepresentative:	MedNet EC-REP GmbH Borkstrasse 10, 48163 Münster, Germany
SRN:	DE-AR-000000002
Trade name:	Surgical Blades (with handle)
Product Name:	Surgical Blades (with handle)
Models:	10#、11#、12#、13#、14#、15#、16#、18#、19#、20#、21#、22#、23#、24#、25#、36#
Basic UDI:	69412981532358P
EMDN：	V010101
Classification acc. to MDR Ax. VIII:	Class IIa, rule 6
Applied Standard &Common Specification:	See appendix list
Conformity assessment procedure:	Annex XI, Part A
CE certificate No.:	Certificate to be issued
Notified Body:	TÜV SÜD Product Service GmbH
Notified Body ID:	0123

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Wendy Xu

Hangzhou, Nov, 20. 2023

Wendy Xu

Management Representative

Applied Standard &Common Specification:

Regulation/Standard/Guidance	Name of Document
(EU) 2017/745	Medical Device Regulation
EN ISO 13485:2016+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
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
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
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 10993-3:2014	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices – Part 11:Tests for systemic toxicity
ASTM F 1980-21	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 –23	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
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+A1:2020	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 556-1:2001 EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN ISO 11137-1:2015	Sterilization of health care products-Radiation Part 1:Requirements for development,validation and routine control of a sterilization process for medical devices
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
MDCG 2020-5	Guidance on clinical evaluation – Equivalence
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
MDCG 2021-5	Guidance on standardization for medical devices
PD CEN ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers
BS EN 27740:1992	Instruments for surgery,scalpels with detachable blades,fitting dimensions
ISO 6507-1:2023	Metallic materials-Vickers hardness test- Part 1:Test method