Declaration of Conformity

Manufacturer Transmed (China) CO., Ltd.

Address: Room 406, Building 3, Phase 2 Accelerator, No.11 Yaogu Avenue, Jiangbei New Area, 210032, Nanjing, Jiangsu Province, P.R.China

European Representative: Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg Germany

Product Name: Sterile Repositionable Hemostatsis Clipping Device

Model Code: Attachment 2

UMDNS code: 10904

Signed by / Podpisano przez:
Dorota Metler
Date / Data: 2024-06-03 11:24

Classification: Class IIa (Annex IX, Rule 5 of MDD 93/42/EEC)

Conformity Assessment Route： Annex V of MDD 93/42/EEC

The Declaration of Conformity is issued under the sole responsibility of Micro-Tech (Nanjing) Co., Ltd. The device that is covered by the present declaration is in conformity with the Regulation (EU) MDR 21234517/745 for medical devices.

All supporting documentation is retained at the premises of the manufacturer.

General applicable directives:

Medical Device Directive: Council Directive 93/42/EEC concerning medical devices

Standard Applied:

All other applicable union legislations, harmonized standards and common specification (published in the Official Journal of the European Communities)

The detail harmonized standards see Attachment 1.

Notified Body:	SGS Belgium NV, Noorderlaan 87, 2030 Antwerpen, Belgium
Identification number:	CE1639
Certificate Number:	CN19/41070
Expire date of the certificate:	24 May 2024
Place, Date of Certificate:	Nanjing, 12 November 2020

Signature: _ Kevin Sun **Date:** 2022-09-27

Name： Kevin Sun

Position： PRRC

Attachment 1

- ✧ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
- ✧ EN ISO 13485-2016+A11-2021 Medical devices – Quality management systems-Requirements for regulatory purposes
- ✧ EN ISO 14971-2019+AMD11-2021 Medical devices - Application of risk management to medical devices
- ✧ BS EN ISO 20417-2021 Information supplied by the manufacturer with medical devices
- ✧ EN ISO 15223-1:2021 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ✧ EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ✧ EN ISO 10993-3:2014 Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ✧ EN ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ✧ EN ISO 10993-6:2016 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
- ✧ EN ISO 10993-7:2008+AC:2009 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
- ✧ EN ISO 10993-10:2013 Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity
- ✧ EN ISO 10993-11:2018 Biological evaluation of medical devices -- Part 11: Tests for Systemic Toxicity
- ✧ EN ISO 11135:2014+AMD1 2019 Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
- ✧ EN ISO 11607-1:2020: Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ✧ EN ISO 11607-2:2020: Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
- ✧ ISTA-2A:2011: Series Partial Simulation Performance Test Procedure (Packaged-Products 150lb (68kg) or less)
- ✧ ASTM F1140/F1140M-13 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.
- ✧ ASTM F1886/F1886M: 2016 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ✧ EN ISO 14644-1:2015 Cleanroom and associated controlled environments - Part 1:

Classification of air cleanliness

- ✧ EN ISO 11737-1:2018 Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
- ✧ 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
- ✧ ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ✧ EN 62366-1:2015 Medical devices – Application of usability engineering to medical devices
- ✧ MEDDEV 2.7.1 (Rev. 4, 2016) Clinical evaluation: a guide for manufacturers and notified bodies
- ✧ MEDDEV 2.12.1 (Rev. 8, 2013) Guidelines on a medical devices vigilance system
- ✧ MEDDEV 2.12.2 (Rev. 2, 2012) Post market clinical follow-up studies a guide for manufacturers and notified bodies
- ✧ EN ISO 14698-1:2014 Cleanrooms and associated controlled environments - Biocontamination control -Part 1: General principles and methods
- ✧ ISO 8600-1: 2015 Optics and photonics —Medical endoscopes and endotherapy devices —Part 1: General requirements

NO	REF	NO	REF	NO	REF
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