



DECLARATION OF CONFORMITY

Manufacturer Name	Micro-Tech (Nanjing) Co., Ltd.
Manufacturer Address	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Manufacturer SRN	CN-MF-000006950
EU Authorized Representative Name	Shanghai International Holding Corp. GmbH (Europe)
EU Authorized Representative Address	Eiffestrasse 80, 20537 Hamburg Germany
EU Authorized Representative SRN	DE-AR-000000001
Product Name	Injection Needle
Basic UDI-DI	6902284SI45019K3
Catalogue Number	Please see Attachment 2
GMDN Code	45019
EMDN Code	G030201
Classification	Class IIa, Rule 6 according to Annex VIII of MDR 2017/745
Conformity Assessment Route	Annex IX (Without chap. II) of MDR 2017/745
Intended Purpose	The Injection Needle is used with endoscope for submucosal injection in digestive tract and endoscopic injection in the treatment of esophageal and gastric varices.

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 2017/745 for medical devices.

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

General applicable Regulation:

REGULATION (EU) 2017/745 of medical device

Standard Applied:

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

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The detail harmonized standards see Attachment 1.

Notified Body (Name & Address):	DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Identification Number:	CE 0344
Certificate Number :	6082015CE01
Certificate Issued Date	2023-07-18
Certificate Expiry Date	2027-09-01

Signature:

Place and date of issue:

...Becky Li.....

Name:

Becky Li

Person Responsible for Regulatory Compliance

Nanjing, PRC, 2024-09-18.....

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Attachment 1

References to other union legislations, standards and common specification (if applicable) applied:

- ✧ Regulation (EU) 2017/745
- ✧ EN ISO 13485:2016 + A11:2021 Medical devices - Quality management systems- Requirements for regulatory purposes
- ✧ EN ISO 15223-1: 2021 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
- ✧ EN ISO 14971-2019+AMD11-2021 Medical devices - Application of risk management to medical devices
- ✧ ISO/TR 24971:2020 Medical devices - Guidance on the application of ISO 14971
- ✧ EN ISO 10993-1:2020 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
- ✧ EN ISO 10993-7:2008+A1:2022 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants
- ✧ EN ISO 10993-10:2013 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
- ✧ EN ISO 11135:2014+A1:2019 Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E, Single batch release.
- ✧ 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
- ✧ 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/Editorial Change 1: 2-12 Series partial simulation performance test procedure



(Packaged-Products 1501b (68kg) or less)

- ✧ 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 F1140/F1140M-13 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.
- ✧ ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ✧ EN ISO 14644-1:2015 Cleanroom and associated controlled environments - Part 1: Classification of air cleanliness
- ✧ EN ISO 80369-7: 2021 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- ✧ MDCG 2018-1 v3 Guidance on basic UDI-DI and changes to UDI-DI
- ✧ MDCG-2019-1 MDCG guiding principles for issuing entities rules on basic UDI-DI
- ✧ MDCG-2019-7 Guidance on Article 15 MDR-IVDR Person responsible for Regulatory Compliance
- ✧ MDCG 2020-5 Guidance on Clinical Evaluation
- ✧ MDCG 2020-6 Guidance on Sufficient Clinical Evaluation
- ✧ IMDRF MDCE WG/N56FINAL: 2019 Clinical Evaluation
- ✧ MEDDEV 2.12-1 Rev 8 2013+Additional Guidance on MEDDEV 2.12/1 Rev.8 July 2019 Guidelines on a medical device vigilance system
- ✧ MEDDEV 2.7.1 Rev 4 Clinical evaluation: a guide for manufacturers and notified bodies
- ✧ ISO/TR 20416 Medical Devices-Post-market surveillance for manufacturer
- ✧ EN 62366-1:2015+A1-2020 Medical devices - Part 1: Application of usability engineering to medical devices
- ✧ ISO 8600-1-2015 Endoscopes - Medical endoscopes and endotherapy devices - Part 1: General requirements
- ✧ EN ISO 20417-2021 Information supplied by the manufacturer of medical devices
- ✧ REACH EC/1907/2006



Attachment 2

NO	REF	NO	REF	NO	REF
1	IN02-254231202	2	IN02-254231602	3	IN02-254231802
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355	JIN02-198231202	356	JIN02-198231602	357	JIN02-198231802

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Revision History

Version	Date	Description
A/0	2023-08-15	Initial