Declaration of Conformity

In accordance with Medical Devices Directive 93/42/EEC,
We herewith declare that the under-mentioned device, in view of its design and type of construction, meets the essential health and safety requirements of the above EC Directive 93/42/EEC as amended by Directive 2007/47/EC. If the device is modified without the agreement of the under-designed, this declaration becomes invalid.

Manufacturer: Zhuhai Ton-Bridge Medical Technology Co., Ltd.
Address: Unit 1-B, Building 4, CEC High Tech Industrial Park, Zhuhai City, China
European Representative: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Product name: Micro Catheter
Trade name: Glycine™
Models: LMC-21-110, LMC-21-130, LMC-21-153, LMC-27-110, LMC-27-130, LMC-27-145.
Classification: Class III by Rule 7 of Annex IX, Council Directive 93/42/EEC
GMDN Code: 17846 Catheter, intravascular, guiding.

The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards, see appendix 1 List of Applied Standard below:

This Declaration of Conformity is based on the EC Directives 93/42/EEC, Annex II under the supervision of Notified body, UDEM (NB No. 2292).

Notified body:
UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş.

EC Certificate No.: M.2021.106.14478 Issue date: 26.04.2021 Expiry date: 27.05.2024

ZHAO JONATHON ZHONG
President on behalf of Zhuhai Ton-Bridge Medical Technology Co., Ltd.

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.12 09:39:25 EEST
Reason: MoldSign Signature
Location: Moldova

Place: Zhuhai Signature: Date: 2023.03.01

Appendix: Applied standards

No.	Reference and title of the harmonised standard	
1	EN 868-5: 2018	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
2	EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer-General requirements
3	EN ISO11138-2: 2017	Sterilization of health care products - Biological indicators -Part 2: Biological indicators for ethylene oxide sterilization processes
4	EN ISO 10555-1:2013/A1:2017	Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements - Amendment 1 (ISO 10555-1:2013/Amd 1:2017)
5	EN ISO 10993-1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
6	EN ISO 10993-4: 2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
7	EN ISO 10993-5: 2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
8	EN ISO 10993-10: 2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
9	EN ISO 10993-11: 2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
10	EN ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation
11	EN ISO 14155: 2020	Clinical investigation of medical devices for human subjects - Good clinical practice
12	ISO 14644-1: 2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
13	EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
14	EN ISO 14971: 2019	Medical devices - Application of risk management to medical devices
15	ISO/TR 24971: 2020	Medical devices - Guidance on the application of ISO 14971
16	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
17	ISO 11070: 2014	Sterile single-use intravascular introducers, dilators and guidewires
18	ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
19	ASTM F1886 / F1886M - 16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
20	ASTM F3172-15(2021)	Standard Guide for Design Verification Device Size and Sample Size Selection for Endovascular Devices
21	ISTA-3A-2018	Packaged-Products for Parcel Delivery System Shipment 70kg(150lb) or less
22	MDCG 2020-7	Guidance on PMCF plan template
23	MDCG 2020-8	Guidance on PMCF evaluation report template
24	MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745