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: Aspiration Catheter
Trade name: Cylone™
Models: TGC-070-06-95, TGC-070-06-105, TGC-070-06-115, TGC-070-06-125, TGC-070-06-130, TGC-070-06-135, TGC-055-05-105, TGC-055-05-115, TGC-055-05-125, TGC-055-05-130, TGC-055-05-135.
Classification: Class III by Rule 7 of Annex IX, Council Directive 93/42/EEC
GMDN Code: Embolectomy/thrombectomy suction catheter (58173)

The product identified above complies with the essential requirements of the above EC Directives by meeting the standards given in appendix 1.

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

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.12 10:56:57 EEST
Reason: MoldSign Signature
Location: Moldova

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

Place: Zhuhai Signature: Date: 2023.03.01

Appendix 1 List of Applied Standards

No.	Reference and title of the harmonised standard	
1	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)
2	ISO 8536-4:2019	Infusion equipment for medical use-Part 4: Infusion sets for single use, gravity feed.
3	EN ISO 10993-1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
4	EN ISO 10993-4: 2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
5	EN ISO 10993-5: 2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
6	EN ISO 10993-7:2008	Biological Evaluation of medical devices – Part7: Ethylene oxide sterilization residuals
7	EN ISO 10993-10: 2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
8	EN ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
9	EN ISO 10993-12:2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference material
10	EN ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation
11	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
12	EN ISO 14971:2019	Medical devices-Application of risk management to medical devices
13	EN ISO 14155: 2020	Clinical investigation of medical devices for human subjects - Good clinical practice
14	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
15	EN ISO 11138-2:2017	Sterilization of health care products-Biological indicators-Part 2: Biological indicators for ethylene oxide sterilization processes
16	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
17	ISO14644-1:2015	Cleanrooms and associated controlled environments-Part 1: Classification of air cleanliness by particle concentration
18	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
19	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
20	ASTM F3172-15(2021)	Standard Guide for Design Verification Device Size and Sample Size Selection for Endovascular Devices
21	ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices

No.	Reference and title of the harmonised standard	
22	ISTA-3A-2018	Packaged-Products for Parcel Delivery System Shipment 70kg(150lb) or less
23	MDCG 2020-7	Guidance on PMCF plan template
24	MDCG 2020-8	Guidance on PMCF evaluation report template
25	MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745