EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2021.106.14478-1 Desingn Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Zhuhai Ton-Bridge Medical Tech. Co., Ltd.
Company Address	: Unit 1-B, Building 4, CEC High Tech Industrial Park, Zhuhai City, China
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Sterile, Single Use, Aspiration Catheter - Class III Sterile, Single Use, Micro Catheter - Class III
GMDN	: 58173, 17846

Product Types are attached.

Certificate Number	: M.2021.106.14478
Report Number	: MD.4009.IB
Initial Assessment Date	: 31.03.2021
Registration Date	: 26.04.2021
Revision Date /No	: -
Expiry Date	: 27.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate [illegible] by UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom [illegible] request. The above named company and UDEM must keep a copy of this certificate for 5 [illegible] of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with [illegible] Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

Digitally signed by Ostapciuc Alexandr
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This document containing 1 (one) pages is the Annex of the Certificate with the number M.2021.106.14478 and with the registration date of 26.04.2021 issued for "Zhuhai Ton-Bridge Medical Tech. Co., Ltd." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

Table 1 Aspiration Catheter

Product name	Model	Specification	OD（Fr/mm）	ID（in/mm）	Effective Length（cm）	GMDN Code
Aspiration Catheter	6F	TGC-070-06-95	06/2.10	0.070/1.80	95	58173
		TGC-070-06-105	06/2.10	0.070/1.80	105	
		TGC-070-06-115	06/2.10	0.070/1.80	115	
		TGC-070-06-125	06/2.10	0.070/1.80	125	
		TGC-070-06-130	06/2.10	0.070/1.80	130	
		TGC-070-06-135	06/2.10	0.070/1.80	135	
	5F	TGC-055-05-105	05/1.70	0.055/1.40	105	
		TGC-055-05-115	05/1.70	0.055/1.40	115	
		TGC-055-05-125	05/1.70	0.055/1.40	125	
		TGC-055-05-130	05/1.70	0.055/1.40	130	
		TGC-055-05-135	05/1.70	0.055/1.40	135	

Table 2 Micro Catheter

Product name	Model	Specification	Proximal outer diameter OD(Fr/mm)	Distal outer diameter OD(Fr/mm)	Inner diameter ID(Fr/mm)	Effective Length L (cm)	GMDN Code
Micro Catheter	21	LMC-21-110	2.7/0.91	2.4/0.81	0.021/0.53	110	17846
		LMC-21-130	2.7/0.91	2.4/0.81	0.021/0.53	130	
		LMC-21-153	2.7/0.91	2.4/0.81	0.021/0.53	153	
	27	LMC-27-110	2.8/0.94	2.8/0.94	0.027/0.69	110	
		LMC-27-130	2.8/0.94	2.8/0.94	0.027/0.69	130	
		LMC-27-145	2.8/0.94	2.8/0.94	0.027/0.69	145	

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