



EC DESIGN EXAMINATION CERTIFICATE

93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2021.106.14478 the validity of the certificate
M.2021.106.14478-1 will also end.

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 (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.2021.106.14478-1

Report Number : MD.4009.IB

Initial Assessment Date : 31.03.2021

Registration Date : 26.04.2021

Revision Date /No : -

Expiry Date : 27.05.2024



The EC desing examination certificate refers to the above mentioned product, UDEM hereby declares that the requirements of Annex II, 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 aforementioned directive. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

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This document containing 1 (one) pages is the Annex of the Certificate with the number M.2021.106.14478-1 and with the registration date of 26.04.2021 issued for “Zuhai 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	