



# EC DESIGN EXAMINATION CERTIFICATE

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

With the expire of the certificate M.2019.106.12584 the validity of the certificate  
M.2019.106.12584-1 will also end.

Company Name : Shanghai MicroPort Endovascular MedTech (Group) Co., Ltd.

Company Address : Building #1, 3399 Kangxin Road, 201318 Shanghai, People's  
Republic of China

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Section 4)

Product : Sterile Abdominal Aortic Stent-Graft and Delivery System - Class III

GMDN : 46777

Product Types are attached.

Certificate Number : M.2019.106.12584-1

Report Number : MD.3856.IB

Initial Assessment Date : 12.04.2019

Registration Date : 12.09.2019

Revision Date /No : 22.04.2021/02

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](http://www.udem.com.tr).

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This document containing 1 (one) pages is the Annex of the Certificate with the revision number 02, with the number M.2019.106.12584-1 and with the registration date of 12.09.2019 and with the revision date of 22.04.2021 issued for "Shanghai MicroPort Endovascular MedTech (Group) 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.

Model and Specifications of Main Body Stent Graft System	CM22-90	CM24-90	CM26-90	CM28-90	CM30-90	CM32-90	CM34-90
	CM22-100	CM24-100	CM26-100	CM28-100	CM30-100	CM32-100	CM34-100
	CM22-110	CM24-110	CM26-110	CM28-110	CM30-110	CM32-110	CM34-110
	CM22-120	CM24-120	CM26-120	CM28-120	CM30-120	CM32-120	CM34-120
	CM22-130	CM24-130	CM26-130	CM28-130	CM30-130	CM32-130	CM34-130
	CM22-140	CM24-140	CM26-140	CM28-140	CM30-140	CM32-140	CM34-140
Profile of the delivery system	14F			16F			
Working length of the delivery system	550mm						

Model and Specifications of CUFF Stent Graft System	CC22-40	CC24-40	CC26-40	CC28-40	CC30-40	CC32-40	CC34-40	CC36-40
Profile of the delivery system	16F							
Working length of the delivery system	550mm							

Model and Specifications of Limb Stent Graft System	CL10-80	CL13-80	CL16-80	CL18-80	CL20-80	CL22-80	CL24-80
	CL10-90	CL13-90	CL16-90	CL18-90	CL20-90	CL22-90	CL24-90
	CL10-100	CL13-100	CL16-100	CL18-100	CL20-100	CL22-100	CL24-100
	CL10-110	CL13-110	CL16-110	CL18-110	CL20-110	CL22-110	CL24-110
	CL10-120	CL13-120	CL16-120	CL18-120	CL20-120	CL22-120	CL24-120
	CL10-130	CL13-130	CL16-130	CL18-130	CL20-130	CL22-130	CL24-130
	CL10-140	CL13-140	CL16-140	CL18-140	CL20-140	CL22-140	CL24-140
Profile of the delivery system	12F						
Working length of the delivery system	610mm						