



C E R T I F I C A T E

EC Design-Examination Certificate

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

With the expire of the certificate M.2020.106.13176 the validity of the certificate M.2020.106.13176-1 will also end.

Company Name : Lepu Medical Technology (Beijing) Co., Ltd.

Company Address : No:37 Chaoqian Rd., Changping Beijing 102200 P.R. China

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

Product : Sterile, Single Use, Thrombus Extraction Catheter - Class III
- Effective Length: 1450±60mm
- Proximal Shaft Diameter: 3.8F (1.19~1.31mm)
- Distal Shaft Diameter: 4.5F (1.49~1.57mm)

GMDN : 58173

Certificate Number : M.2020.106.13176-1
Report Number : MD.3672.IB
Initial Assessment Date : 19.06.2019
Registration Date : 07.02.2020
Revision Date /No : -
Expiry Date : 27.05.2024

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

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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