



EC DESIGN EXAMINATION CERTIFICATE

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

With the expire of the certificate M.2020.106.14142 the validity of the certificate
M.2020.106.14142-1 will also end.

Company Name : Shanghai Kindly Medical Instruments Co., Ltd.

Company Address : No.925 Jinyuan yi Road, 201803,Shanghai, China

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

Product : Sterile Cardiovascular Angiography Catheter - Class III
Sterile Guiding Catheter - Class III
Sterile Micro Catheter - Class III
Sterile Cardiovascular Guidewire - Class III

GMDN : 10688, 17846, 36205, 31668

Product Types are attached.

Certificate Number : M.2020.106.14142-1
Report Number : MD.4077.IB
Initial Assessment Date : 22.10.2020
Registration Date : 29.12.2020
Revision Date /No : -
Expiry Date : 27.05.2024

Shanghai
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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