CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

Company Name	: Sarge Tıp Teknolojileri Ltd. Şti.
Company Address	: Pınarbaşı Mah. Hürriyet Cad. No3D Konyaaltı ANTALYA / TURKEY
Related Directives and Annex	: MDD 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: - Endoscopic Retrieval Devices - Class Is - Sterile - Polypectomy Snares - Class IIb - Sterile - Endoscopic Sphincterotomes - Class IIb - Sterile - Stone Extraction/Lithotriptor Baskets - Class IIa - Sterile - ERCP Cannula - Class Is - Sterile - Stone Extraction Balloons - Class IIa - Sterile

Certificate Number	: M.2016.106.6988
Report Number	: UD.3011.IB
Initial Assessment Date	: 04.08.2016
Registration Date	: 26.09.2016
Revision Date /No	: -
Expiry Date	: 25.09.2021

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

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC 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. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd. 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 currency of the certificate can be checked through www.udemltd.com. tr.

CE 2292

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