EC CERTIFICATE

Production Quality Assurance

Medical Devices Directive 93/42/EEC Annex V

Company Name	: Eraser Medikal Tıb. Cih. Sağ. Ür. Paz. San. ve Tic. Ltd. Şti.
Company Address	: Kemalpaşa Mah. Pınar Cad. No:78 Pınarbaşı Bornova İZMİR / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex V
Product	: - Enteral Feeding Sets Working With Sterile Gravity Effect-Entral Feeding Bag and Accessories - Class Is - Sterile Active Device Connected Enteral Feeding Sets - Entral Feeding Bag and Accessories - Class IIa - Sterile Closed System Drug Preparation and Administration Sets (Needleless IV Valves, Filter Sets, Disposable Infusion Sets, Extention Sets With Manifold, Extention Sets,) Infusion Bags - Class IIa
GMDN	: 43324, 35127, 36244, 12170, 33963, 17701, 11675, 62256, 64461, 32172
Certificate Number	: M.2019.106.13002
Report Number	: MD.4012.IB
Initial Assessment Date	: 25.10.2019
Registration Date	: 29.11.2019
Revision Date /No	: 18.05.2021/01
Expiry Date	: 27.05.2024

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

UDEM hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev,ce is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. 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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