EC CERTIFICATE

Production Quality Assurance

Medical Devices Directive 93/42/EEC Annex V

Company Name	: Şafak Medikal Tıbbi Cihazlar Sarf Malzemeler - Kenan Daşdemir
Company Address	: Berk Köyü Fabrika Cad. No:23 BOLU / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex V
Product	: Hypodermic Sterile Syringe With Needle - Class IIa
GMDN	: 35904

Product Types are attached.

Digitally signed by Țurcanu Ștefan
Date: 2022.09.21 18:38:15 EEST
Reason: MoldSign Signature
Location: Moldova

Certificate Number	: M.2019.106.11994
Report Number	: MD.3697.IB
Initial Assessment Date	: 05.04.2019
Registration Date	: 20.05.2019
Revision Date /No	: 18.05.2021/01
Expiry Date	: 19.05.2024

UDEM APPROVED 2292

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.

UDEM

ŞAFAK MEDİKAL
TIBBİ CİHAZLAR SARF MALZEMELER
Kenan DAŞDEMİR
Berkköy Fabrika Cad. No 23 - BOLU
Tel 0374 222 14 04
Ağı Vergi Dairesi:1912 0307 890

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr