EC CERTIFICATE

Production Quality Assurance

Medical Devices Directive 93/42/EEC Annex V

Company Name	: Berika Teknoloji Medikal İmalat İth. İhr. Tic. Ltd. Şti.
Company Address	: Alakova Mah. Karaman Cad. No:812 Meram KONYA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex V
Product	: Sterile Single Use Syringe - Class IIa - 1 Ml. 3 Pieces Steril With Needle/Without Needle - 2 Ml. 3 Pieces Steril With Needle/Without Needle - 2,5 Ml. 3 Pieces Steril With Needle/Without Needle - 3 Ml. 3 Pieces Steril With Needle/Without Needle - 5 Ml. 3 Pieces Steril With Needle/Without Needle - 10 Ml. 3 Pieces Steril With Needle/Without Needle - 20 Ml. 3 Pieces Steril With Needle/Without Needle - 50Ml. 3 Pieces Steril With Needle/Without Needle Sterile Single Use Hypodermic Needles - Class IIa - Pink 18G 1 1.20x25mm - Pink 18G 1 ½ 1.20x38mm - Yellow 20G 1 ½ 0,90x38mm - Green 21G 1 ½ 0,80x38mm - Green 21G 1 5/8 0,80x16mm - Black 22G 1 ¼ 0,70x32mm - Blue 23G 1 ¼ 0,60x32mm - Blue 23G 1 0,60x25mm - Orange 25G 1 0,50x25mm - Brown 26G ½ 0,45x13mm - Brown 26G 5/8 0,45x16mm - Grey 27G 1 ½ 0,40x38mm - Grey 27G 2 ½ 0,40x50mm - Yellow 30G ½ 0,30x13mm - Yellow 30G 5/16 0,30x8mm Disposible Sterile Blood Gas Syringe With Needle - Class IIa
GMDN	: 47017, 59230, 58095
Certificate Number	: M.2016.106.6915
Report Number	: MD.3159.IB
Initial Assessment Date	: 16.07.2016
Registration Date	: 05.08.2016
Recertification Assessment Date	: 03.10.2019
Reissue Date / No	: 24.02.2020/01
Revision Date /No	: 20.05.2021/01
Expiry Date	: 27.05.2024

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.

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