EC CERTIFICATE

Production Quality Assurance

Medical Devices Directive 93/42/EEC Annex V

Company Name	: Ayset Tıbbi Ürünler ve Plastik Tekstil Elektronik Gıda Temizlik Maddeleri İnşaat Müteahhitlik San. A.Ş.
Company Address	: Sarıhamzalı Mah. 47007 Sokak No:36/A Seyhan ADANA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex V
Product	: - Sterile, Single Use 3 Pieces Arterial blood gas sampler with needle - Class IIa - Sterile, Single Use 3 Pieces Syringes (Without Needle, Luer Slip/ Luer Lock) - Class Is - Sterile, Single Use 2 Pieces Syringes (Without Needle, Luer Slip/ Luer Lock) - Class Is - Sterile, Single Use 3 Pieces Syringes (With Needle, Luer Slip/ Luer Lock) - Class IIa - Sterile, Single Use 2 Pieces Syringes (With Needle, Luer Slip/ Luer Lock) - Class IIa - Sterile, Single Use U-100 Insulin Syringes (Without Needle) - Class Is - Sterile, Single Use U-100 Insulin Syringes (With Needle) - Class IIa - Sterile, Single Use Tuberculin Syringes (Without Needle) - Class Is - Sterile, Single Use Tuberculin Syringes (With Needle) - Class IIa - Sterile, Single Use Hypodermic Neddles - Class IIa - Sterile, Single Use Multi-Sample Blood Collection Needles - Class IIa - Sterile, Single Use Multi-Sample Blood Collection Needles Butterfly Set Type - Class IIa - Sterile, Single Use Insulin Pen Injector Needles - Class IIa
GMDN	: 58095, 35904, 34973, 38501, 32592, 59230, 35209
Certificate Number	: M.2016.106.6922
Report Number	: MD.3205.YB
Initial Assessment Date	: 16.07.2016
Registration Date	: 06.08.2016
Recertification Assessment Date	: 09.12.2020
Reissue Date / No	: 25.05.2021/01
Revision Date /No	: -
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.

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

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Date: 2022.12.05 13:36:23 EET
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Location: Moldova