E C C E R T I F I C A T E

Production Quality Assurance for Medical Devices Directive 93/42/EEC Annex V

Company Name : [redacted] Tıbbi Ürünler ve Plastik Tekstil Elektronik [redacted] Maddeleri San. A.Ş.

Company Address : [redacted] Seyhan ADANA / TURKEY

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex V

Product :
- Sterile, Single Use Heparin Cap - Class IIa
- Sterile, Single Use Butterfly Set - Class IIa
- Sterile, Single Use Stopcocks (Two Way , Three Way) - Class I S
- Sterile, Single Use 3 Pieces Arterial blood gas sampler with needle - Class IIa
- Sterile, Single Use 3 Pieces Syringes (With/Without Needle, Luer Slip/Luer Lock) - Class IIa
- Sterile, Single Use 2 Pieces Syringes (With/Without Needle, Luer Slip/Luer Lock) - Class IIa
- Sterile, Single Use U-100 Insulin Syringes (With/Without Needle) - Class IIa
- Sterile, Single Use Tuberculin Syringes (With/Without 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 : 47132, 35211, 32172, 58095, 35904, 34973, 38501, 32592, 59230, 35209

Certificate Number : M.2016.106.6922
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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 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 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 currency of the certificate can be checked through www.udem.com. tr.

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