



ECCERTIFICATE

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

Company Name : Ayset Tıbbi Ürünler ve Plastik Tekstil Elektronik Gıda Temizlik
Maddeleri San. A.Ş.

Company Address : Sarıhamzalı Mah. 47007 Sk. No:36/A Seyhan ADANA / TURKEY

Production Site : No:2 Guanyin Road, Economic Development Zone Taihu County
246400 Anqing, Anhui, China

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

Product : Sterile, Single Use 3 Pieces Syringes (With/Without Needle) - Class Ila
Sterile, Single Use 2 Pieces Syringes (With/Without Needle) - Class Ila
Sterile, Single Use U-100 Insulin Syringes (With/Without Needle) - Class Ila
Sterile, Single Use Tuberculin Syringes (With/Without Needle) - Class Ila
Sterile, Single Use Infusion Sets - Class Ila

GMDN : 35904, 34973, 38501, 32592, 36244

Certificate Number : M.2017.106.7914

Report Number : MD.3205.IB

Initial Assessment Date : 01.10.2016

Registration Date : 28.02.2017

Revision Date /No : 17.10.2018/02

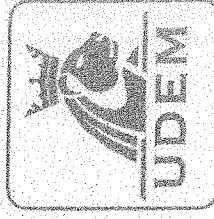
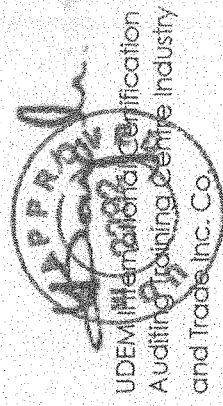
Expiry Date : 27.02.2022

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. 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.

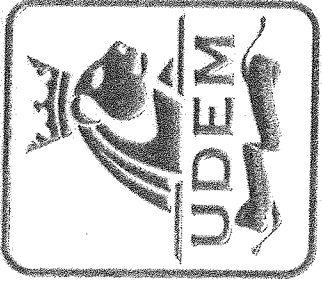
Address: Muhtekent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY

Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76

E-mail: info@udemtd.com.tr www.udem.com.tr



CE
2292



CERTIFICATE

85228

This certificate was given to the below stated company by UDEM International Certification
Audit Training Cent. Ind. Inc. Co. Reference standards are
TS EN ISO 13485:2003 and EN 13485:2012

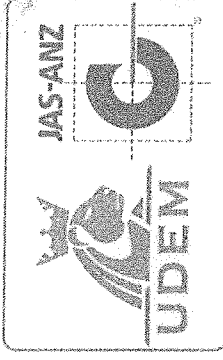
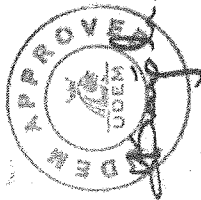
Ayset Tıbbi Ürünler ve Plastik Tekstil Elektronik Gıda Temizlik Maddeleri San. A.Ş.

Sarıhamzalı Mahallesi 47007 Sokak No:36/A Seyhan
ADANA / TURKEY

ISO 13485:2003

Scope: Manufacture of disposable medical products; injection, infusion and transfusion devices

Audit Date : 06.11.2014
Decision Date : 30.01.2015
Reissue Date : 26.01.2018
Expiry Date : 27.01.2021



UDEM International Certification
Audit Training Cent. Ind. Inc. Co.

Hereby, UDEM International Certification Audit Training Cent. Ind. Inc. Co. certifies that the above stated company have the appropriate management system according to the requirements of the above standard. This certificate is valid for 3 years since the decision date as long as the system is effectively maintained and surveillance audits are carried out. The validity of the certificate can be checked through www.udem.com.tr, www.ias-anz.org/register. The certificate is the property of UDEM International Certification Audit Training Cent. Ind. Inc. Co. and shall be returned if requested.

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