

akssert

# CERTIFICATE

Ayset Tıbbi Ürünler ve Plastik Tekstil  
Elektronik Gıda Temizlik Maddeleri İnşaat  
Müteahhitlik Sanayi Anonim Şirketi

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

## ISO 13485:2016

Scope: Production, sales and marketing Medical disposable products; injection, infusion and transfusion devices

Hereby, AKSSERT Audit and Certification Ltd. Co., certifies that the above stated company gave the appropriate management system according to the requirements of the above standard. This certificate 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 certificate can be checked through [www.akssert.com](http://www.akssert.com), [www.jas-anz.org/register](http://www.jas-anz.org/register). The Certificate is property of AKSSERT Audit and Certification Ltd. Co. and shall be returned if requested.

The reference standard is ISO 13485:2016



AKSSERT Audit and  
Certification Ltd. Co.



Certificate Number : 85228  
Registration Date : 30.01.2015

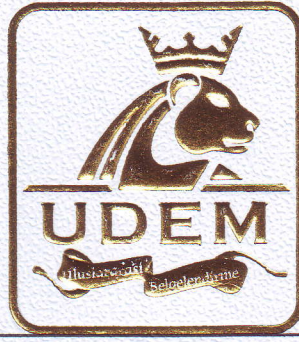
Reissue Date : 29.01.2021  
Expiry Date : 28.01.2024

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FRM.125/02-21.08.2019/20.02.2017



# 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 certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device 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](http://www.udem.com.tr).



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