



# CERTIFICATE

İstem Medikal Tıbbi  
Cihaz ve San. Tic. Ltd. Şti.

Anadolu Organize Sanayi Bölgesi Mah. 29 Ekim Cad. No:41 Malıköy Sincan ANKARA / TURKEY

## ISO 13485:2016

Scope: Design, manufacturing and sales of sterile water soluble lubricant gel, sterile lubricant gel with lidocaine, sterile lubricant gel with lidocaine (CHG Free), sterile injectable implant for vur and sui treatment, sterile 0.9% sodium chloride solution, sterile sodium hyaluronate solution, sterile sodium hyaluronate gel, sterile hydrophilic urinary catheter, sterile antibacterial hydrophilic urinary catheter, sterile nelaton catheter, sterile instillation catheter, sterile inhalation water, sterile embolization application set, sterile intravascular catheters, sterile retrievable vena cava filter, sterile amorphous hydrogel, sterile filter tur collector set, surgical mask

*Walsmühler Strabe 18 19073, Dümmer, Germany*

*Hauptstrasse 3A 19073 Dümmer, Germany*

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 : 85209  
Registration Date : 27.01.2016  
Previous Certification Cycle Expiry Date: 26.01.2022  
Recertification Audit Date: 13.01.2022

Reissue Date : 24.01.2022  
Revision Date/No : -  
Expiry Date : 26.01.2025

Address: Mutlukent Mahallesi 1920. Cadde No:28 Çankaya/ANKARA - TÜRKİYE

Phone: +90 312 284 99 44(pbx)

E-mail: [info@akssert.com](mailto:info@akssert.com) Web: [www.akssert.com](http://www.akssert.com)