



CERTIFICATE



## 3TEKS TEKSTİL GIDA İTHALAT İHRACAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Başpınar (Organize) OSB Mahallesi 2. Organize Sanayi Bölgesi Vali Muammer Güler  
Bulvarı No:5/0 Şehitkamil - Gaziantep - Turkey

with a scope of

**Production, Distrubition and Sale Sterile Disposable Surgery  
Gowns, Sterile Disposable Surgery Drapes, Sterile Disposable  
Surgery Packs, Storing and Sale Medical Packaging Sterilization  
Packaging Materials and Sterilization with Ethylene Oxide  
According to EN ISO 11135"**

Medical devices - Quality management systems - Requirements for  
regulatory purposes

*"Following elements of the standard are excluded"*

*"7.3" "7.5.3" "7.5.4" "7.5.9.2"*

## EN ISO 13485:2016

Certificate No : M 11185  
Initial Certification Date : 26 February 2019  
Certification Date : 26 February 2019  
Expiration Date : 25 February 2022



Medical Device Q.M.S.  
TS EN ISO/IEC 17021-1

AB-0006-YS



TÜRKAK BDS NO  
YS-6A23-39FD

General Manager

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*Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.*

Please contact above numbers for detailed information.

Last Modified: 26 February 2019 - R 00