

CERTIFICATE



## BİOANALYSE TIBBİ MALZEMELER SANAYİ VE TİCARET LİMİTED ŞİRKETİ

IVEDİK OSB 1333. CAD. 1377. SOK. NO: 5 YENİMAHALLE – ANKARA – TURKEY

with a scope of

**DESIGN, PRODUCTION AND SALES OF THE ANTIMICROBIAL  
SUSCEPTIBILITY TESTING DISC, MIC TEST STRIPS AND  
LABORATORY KITS**

Medical devices - Quality management systems - Requirements for  
regulatory purposes

*"Following elements of the standard are excluded"*

*"7.5.3" "7.5.4" "7.5.5" "7.5.7" "7.5.9.2"*

### EN ISO 13485:2016

Certificate No : M 11244  
Initial Certification Date : 12 April 2019  
Certification Date : 12 April 2019  
Expiration Date : 11 April 2022



Medical Device Q.M.S.  
TS EN ISO/IEC 17021-1  
AB-0006-YS



TÜRKAK BDS NO  
YS-D5CF-F603

General Manager

Kiwa Certification Services Inc.

ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey

Tel: +90 216 593 25 75 Faks : +90 216 593 25 74

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

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

Please contact above numbers for detailed information.

Last Modified: 12 April 2019 - R 00