



CERTIFICATE

hibrigen

Hibrigen Biyoteknoloji Arge San.Tic.Ltd.Şti.

**HİBRİGEN BİYOTEKNOLOJİ ARAŞTIRMA GELİŞTİRME
SANAYİ VE TİCARET LİMİTED ŞİRKETİ**

HQ: KOŞUYOLU MAH. KATİP SALİH SOK. NO: 111 KADIKÖY – İSTANBUL – TURKEY
BRANCH: TÜBİTAK MAM TEKNOLOJİ SERBEST BÖLGESİ BARIŞ SB. MAHALLESİ
5002 SOK. YENİ TEK. BİNASI A BLOK NO: 4 A/101 GEBZE – KOCAELİ – TURKEY

with a scope of

**DESIGN, PRODUCTION, EDUCATION, IMPORT, EXPORT AND
SALES SERVICE OF THE MOLECULAR DIAGNOSTIC KITS,
MOLECULAR GENETICS SUPPLIES**

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 9336
Initial Certification Date : 30 January 2013
Certification Date : 21 January 2019
Expiration Date : 20 January 2022



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

AB-0006-YS



TÜRKAK BDS NO
YS-B352-2D77

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: 11 December 2019 - R 04