



TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ BELGESİ

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM CERTIFICATE

EK / APPENDIX



Belge No / Certificate No: TY-29/19

Belgeli Kuruluş Adı, Adresi:

Name and Address of the Certified Organization:

Belge Kapsamı:

TS EN ISO 13485:2016

BİYOKİMYA REAKTİFLERİ, YARDIMCI
BİOKİMYA REAKTİFLERİ, İSE REAKTİFLERİ, KAN
SAYIM REAKTİFLERİ VE KOAGÜLASYON
REAKTİFLERİNİN

TASARIM, ÜRETİMİ VE SATIŞI

TSE
TS EN ISO
13485

Belge Tarihi / Date of Certificate: 11.01.2022

ARCHEM SAĞLIK SANAYİ VE TİCARET A.Ş.
MAHMUTBEY MAH. HALKALI CAD. NO:124 İÇ
KAPI NO:42 BAĞCILAR
İSTANBUL / TÜRKİYE

Scope of the Certificate:

TS EN ISO 13485:2016

DESIGN, MANUFACTURE AND SALE OF

BIOCHEMISTRY REAGENTS, ANCILLARY
BIOCHEMISTRY REAGENTS, İSE REAGENTS,
HEMATOLOGY REAGENTS AND
COAGULATION REAGENTS

