



TİBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ BELGESİ

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM CERTIFICATE



TÜRK STANDARDLARI ENSTİTÜSÜ
bu belge ile

İLKO İLAÇ SAN. VE TİC. A.Ş.
MERKEZ: VEYSEL KARANI MAH. ÇOLAKOĞLU SOK.
NO:10 KAT:7-8-9 SANCAKTEPE - İSTANBUL
MERKEZ ÜRETİM:3. OSB KUDDUSI CAD. 23. SOK.
NO:1 SELÇUKLU -
KONYA / TÜRKİYE

kuruluşunun TS EN ISO 13485:2016 şartlarına uygun bir TİBBİ
CİHAZLAR KALİTE YÖNETİM SİSTEMİ'ne sahip olduğunu
onaylar.

Belge kapsamı Ek'te verilmiştir



Bu belge belgelendirme şartlarına
uygunluk sağlandığı sürece geçerlidir.



TÜRK STANDARDLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

SİSTEM BELGELENDİRME GRUBU BAŞKANI
HEAD of SYSTEM CERTIFICATION GROUP

MESUT DURU

Türk Standardları Enstitüsü Türk Akreditasyon Kurumu TÜRKAK tarafından akredite edilmiştir.
Turkish Standards Institution, has been accredited by the Turkish Accreditation Agency TÜRKAK.

TURKISH STANDARDS INSTITUTION
hereby certifies that the organization

İLKO İLAÇ SAN. VE TİC. A.Ş.
MERKEZ: VEYSEL KARANI MAH. ÇOLAKOĞLU SOK.
NO:10 KAT:7-8-9 SANCAKTEPE - İSTANBUL
MERKEZ ÜRETİM:3. OSB KUDDUSI CAD. 23. SOK.
NO:1 SELÇUKLU -
KONYA / TÜRKİYE

has a MEDICAL DEVICES QUALITY MANAGEMENT
SYSTEM which fulfills the requirements of the TS EN ISO
13485:2016

Scope of the certificate is given in annex

Belge No / Certificate No	TY-017/16-R16
Belge Tarihi / Date of Certificate	09.01.2020
Geçerlilik Tarihi / Valid Until	09.12.2022
Revizyon Tarihi / Date of Revision	09.01.2020
İlk Belge Tarihi / Initial Certification Date	09.12.2016

This certificate is valid provided that compliance
with the certification requirement is maintained.



TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ BELGESİ

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM CERTIFICATE

EK / APPENDIX



Belge No / Certificate No: **TY-017/16-R16**

Belgeli Kuruluş Adı, Adresi:

Name and Address of the Certified Organization:

Belge Kapsamı:

TS EN ISO 13485:2016

09.01.2020 TARİHİNDEN İTİBAREN;

- TIBBİ CİHAZ KAPSAMINDA; TABLET, ŞASE, GÖZ DAMLASI VE SPREY FORMLARININ AMBALAJLANMASI

- YENİDEN İŞLENMESİ KAPSAMINDA; DIŞ AMBALAJ TANITIM VE FİYAT DEĞİŞİMİ AMAÇLI ETİKETLEME, PROMOSYON PAKETİ OLUŞTURMA, KUTU İÇİ KULLANMA TALİMATI EKLEME, DIŞ AMBALAJ ÜZERİNDE 2D KAREKOD BASMA

- BU İŞLEMLERİ YAPILAN ÜRÜNLERİN DEPOLANMASI, SATIŞ VE PAZARLANMASI



Belge Tarihi / Date of Certificate: **09.01.2020**

ILKO İLAÇ SAN. VE TİC. A.Ş.
MERKEZ: VEYSEL KARANI MAH. ÇOLAKOĞLU SOK.
NO:10 KAT:7-8-9 SANCAKTEPE - İSTANBUL
MERKEZ ÜRETİM:3. OSB KUDDUSI CAD. 23. SOK.
NO:1 SELÇUKLU -
KONYA / TÜRKİYE

Scope of the Certificate:

TS EN ISO 13485:2016

SINCE 09 01 2020;

PACKAGING OF

- TABLETS, SACHETS, EYE DROPS AND SPRAYS IN THE SCOPE OF MEDICAL DEVICE

- IN THE SCOPE OF REWORK;

LABELING FOR EXTERNAL PACKAGING AND PRICE CHANGE, CREATING PROMOTIONAL PACKAGE, INSERTING IN-BOX INSTRUCTIONS, PRINTING 2D CARD CODE ON EXTERNAL PACKAGING

- STORAGE, SALES AND MARKETING OF THE PRODUCTS



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

TSE has issued an IQNet recognized certificate that the organization:

ILKO İLAÇ SAN. VE TİC. A.Ş.

MERKEZ:VEYSEL KARANI MAH. ÇOLAKOĞLU SOK. NO:10 KAT:7-8-9 SANCAKTEPE - İSTANBUL
MERKEZ ÜRETİM:3. OSB KUDDUSİ CAD. 23. SOK. NO:1 SELÇUKLU -
KONYA / TÜRKİYE

has implemented and maintains a
MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM
which fulfills the requirements of the following standard:

TS EN ISO 13485:2016

Issued on: 09-01-2020
Expires on: 09-12-2022

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as
a stand-alone document

Registration Number : TR-TY-017 / 16-R16



Alex Stoichitoiu

President of IQNet

Mesut Duru

Head of System Certification Group



IQNet Partners*:

AENOR Spain, AFNOR Certification France, APCER Portugal, CISO Italy,
CQC China, CQM China, CQS Czech Republic, Cro Cert Croatia, DQS Holding GmbH Germany, FCAV Brazil,
FONDONORMA Venezuela, ICONTEC Colombia, Inspecta Serfiteointi Oy Finland, INTECO Costa Rica,
IRAM Argentina, JQA Japan, KFQ Korea, MIRTEC Greece, MSZT Hungary, Nemko AS Norway, NSAI Ireland,
NYCE - SIGE Mexico, PCBC Poland, Quality Austria Austria, RR Russia, SII Israel, SIQ Slovenia,
SRIM QAS International Malaysia, SQS Switzerland, SRAC Romania, TEST St Petersburg Russia, TSE Turkey, YUQS Serbia,
IQNet is represented in the USA by: AFNOR Certification, CISO, DQS Holding GmbH and NSAI Inc.



THE INTERNATIONAL CERTIFICATION NETWORK

Annex to IQNET Certificate Number :TR-TY-017 / 16-R16

Name and Address of the certified organization

ILKO İLAÇ SAN. VE TİC. A.Ş.

MERKEZ:VEYSEL KARANI MAH. ÇOLAKOĞLU SOK. NO:10 KAT:7-8-9 SANCAKTEPE - İSTANBUL
MERKEZ ÜRETİM:3. OSB KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU - KONYA / TÜRKİYE

Scope of the Certificate

SINCE 09.01.2020;

PACKAGING OF

- TABLETS, SACHETS, EYE DROPS AND SPRAYS IN THE SCOPE OF MEDICAL DEVICE

- IN THE SCOPE OF REWORK:

LABELING FOR EXTERNAL PACKAGING AND PRICE CHANGE, CREATING PROMOTIONAL PACKAGE,
INSERTING IN-BOX INSTRUCTIONS, PRINTING 2D CARD CODE ON EXTERNAL PACKAGING

- STORAGE, SALES AND MARKETING OF THE PRODUCTS

This annex is only valid in connection with the above-mentioned certificate



TURKISH STANDARDS INSTITUTION

