



CERTIFICATE



**EC Certificate**  
**Full Quality Assurance System according to**  
**Medical Devices Directive 93/42/EEC Annex-II Section 3**

**Certificate Number: 1984-MDD-15-351**

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

**Organization:**

**MT SAĞLIK ÜRÜNLERİ**  
**SANAYİ VE TİCARET ANONİM ŞİRKETİ**

Oruçreis Mah. Tekstilkent Cad. Tekstilkent B Blok No:12A/231  
Atışalanı/Esenler-İstanbul, Turkey

**Product:** Sterile Insulin Pen Needle

**Models:** 31G x 5 mm (MTSET108, MTSET104, RF15) , 31G x 6 mm (MTSET101, MTSET105, RF16), 31G x 8 mm (MTSET109, MTSET106, RF18), 32G x 4 mm (MTSET102, MTSET107, RF24), 30G x 8 mm (MTSET100, MTSET103, RF08)

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

**Report Number:** M.4543.06  
**Date of first issue:** 19 August 2015  
**Date of last issue:** 08 February 2021  
**Revision Number:** 03  
**Expiry Date:** 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

**Muhteşem Gökhan Yücel**  
Head of Notified Body

08 February 2021, Istanbul, Turkey





# Certificate

**ISO 13485 : 2016**

**MT SAĞLIK ÜRÜNLERİ SANAYİ  
VE TİCARET A.Ş.**

**Oruç Reis Mah. Tekstil Kent Cad. Tekstil Kent B Blok No: 12A/231 Atışalanı  
Esenler İstanbul/ TURKEY**

This certificate shows that the medical devices - quality management system (EN ISO 13485:2016) of the above company was approved by PCA Certification for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria

## SCOPE

Insulin pencil production is a major component of the production of cloth and metal orthopedic products, sugar measuring devices and rods, patient care products, blood pressure devices, respiratory products, plaster casts, purchase, sale and distribution

## GROUP CODE

A-B-D

<b>Certificate No</b>	: TC-75020
<b>Registration Date</b>	: 22.12.2017
<b>Reissue Date</b>	: 14.12.2021
<b>Expiry Date</b>	: 21.12.2022
<b>Certificate Period</b>	: 3 Years (From the date of registration)
<b>Exclusion</b>	: 7.5.3 / 7.5.9.2



**ACCREDITED**

Management  
Systems  
Certification Body

**MSCB-103**



**PCA Certification Approval**

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