

# CERTIFICATE



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

**Certificate Number: 1984-MDD-15-324**

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:**

**SET MEDİKAL SANAYİ VE TİCARET ANONİM ŞİRKETİ**

Osmangazi Mah. Mareşal Fevzi Çakmak Cad. No:18, Esenyurt, İstanbul, Turkey

**Product:** Sterile Insuline Pen Needles

**Types:** 30G, 31G, 32G

**Product:** Infusion Set

**Product:** Extension Line

**Types:** Amber (30 cm-250 cm), Coex (30 cm-250 cm), Transparent (30 cm-250 cm)

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

**Report Number:** M.4519.05  
**Date of first issue:** 20 February 2015  
**Date of last issue:** 12 November 2019  
**Revision Number:** 04  
**Expiry Date:** 18 February 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

12 November 2019, İstanbul, Turkey

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