



## 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

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa Meyer for details. This certificate is valid 04 March 2018.

**Report number:** M.4519.01  
**Date of first issue:** 20 February 2015  
**Date of last issue:** 08 July 2015  
**Revision number:** 01

Kiwa Meyer Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number : 1984

08 July 2015, Istanbul, Turkey

Head of Notified Body

Certificate