





EC Certificate

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

Certificate Number: 1984-MDD-10-075

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:

METKO MEDİKAL VE TIBBİ CİHAZLAR DIŞ TİCARET LİMİTED ŞİRKETİ

İvedik OSB Ağaç İşleri San. Sitesi 1354. Cadde 1358. Sokak No:9 06378 Yenimahalle, Ankara, Turkey

Products: Sterile and Non-Sterile Pulse Oximetry (SpO2) Sensors and Medical Temperature Probes, Sterile Disposable Pressure Transducer

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

Report Number:

M.3393.10

Date of first issue:

23 December 2010

Date of last issue:

16 April 2019

Revision Number:

09

Expiry Date:

20 November 2020

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

16 April 2019, Istanbul, Turkey

Head of Notified Body

