

EC Certificate

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

Certificate Number: 1984-MDD-17-474

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:

İSTANBUL MEDİKAL LİMİTED ŞİRKETİ

Eğitim Mah. Şirinyuva Sok. No.3 K.1 D.1 Kadıköy, İstanbul, Turkey

Product: Patient Warming System with warmer blankets and mattress

Model Number:

Control Unit: W-150T, W-150TL, W-300, W-500D

Mattress: IM-190M, IM-190MS, IM-180SM, IM-150M, IM-150MS, IM-120M, IM-120MS, IM-80M, IM-80MS, IM-60MS, IM-55M

Blanket: IM-190B, IM-180B, IM-180BAS, IM-150B, IM-150BAS, IM-120B, IM-85DB, IM-80B, IM-65BK, IM-65BI, IM-55BK

Product: Phototherapy Device

Model Number: KMF-01

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

Report Number: M.4322.05

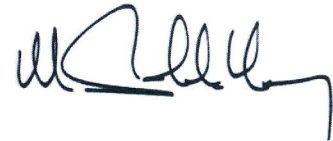
Date of first issue: 13 December 2017

Date of last issue: 18 January 2019

Revision Number: 01

Expiry Date: 12 December 2020

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



18 January 2019, Istanbul, Turkey

Head of Notified Body