CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-17-428

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:

OKUMAN MEDİKAL SİSTEMLER ANONİM ŞİRKETİ

HQ: Zübeyde Hanım Mahallesi Kazım Karabekir Caddesi No:95/95
06060 İskitler, Ankara, Turkey
Factory: İvedik Organize San. Bölgesi Arı Sanayi Sitesi 1.Etap 1417 Sok.
No:51 Yenimahalle, Ankara, Turkey

Products: Intensive Care Phototerapy, Radiant Warmer, Infant Incubator, Multi-Parameter Patient Monitors, Infant Ventilator, Transport Incubator, Defibrillator Monitor, Warming Bed, Resuscitation Device

The products defined at the enclosure which is the part of this certificate and contains one (1) pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.3222.11
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Revision Number: 08
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Muhteşem Gökhan Yücel
Head of Notified Body

22 May 2021, Istanbul, Turkey

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CERTIFICATE

Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-17-428, Revision Number: 08
Concerned medical devices;

Product: Intensive Care Phototerapy
Model Number: BiliCare

Product: Radiant Warmer
Model Number: OKM 730

Product: Infant Incubator
Model Number: OKM 801, OKM 862

Product: Infant Ventilator
Model Number: OKM IBS

Product: Transport Incubator
Model Number: TR 203

Product: Multi-Parameter Patient Monitors
Model Number: OKM VS3, OKM 300, OKM 500, OKM 600, OKM 700, OKM 800, OKM 860, OKM 900, OKM 84, OKM 104, OKM 121, OKM 8800

Product: Defibrillator Monitor
Model Number: DFM600, DFM800

Product: Warming Bed
Model Number: OKM 740

Product: Resuscitation Device
Model Number: OKM 150

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

22 May 2021, Istanbul, Turkey

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