

EC Certificate

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

Certificate Number: 1984-MDD-09-005

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:

**NOVOS TIBBİ CİHAZLAR SANAYİ VE TİCARET
İTHALAT VE İHRACAT LİMİTED ŞİRKETİ**

İvedikösb Mahallesi 1518. Cad. Matbaacılar Sitesi Sit. No: 2/39
Yenimahalle, Ankara, Turkey

Products: Phototherapy Device, Baby Radiant Warmer, Infant Resuscitation Device, Infant Incubator, Infant Transport Incubator, Skin Probe

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

Report Number: M.2842.13
Date of first issue: 18 December 2009
Date of last issue: 17 May 2021
Revision Number: 12
Expiry Date: 27 May 2024



Muhteşem Gökhan Yücel
Head of Notified Body

17 May 2021, Istanbul, Turkey

Enclosure of the EC Certificate:

1/1

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

Certificate Number: 1984-MDD-09-005, Revision Number: 12

Concerned medical devices;

Name of the product	Models
Phototherapy Device	BILISPHERE 360 LED BILILED MAXI NEOLED 360 NEOLED MAXI BILILED MAXI + BILILED MINI + NEOLED MAXI +
Baby Radiant Warmer	KR-1000 NEOCARE NR-1000
Infant Resuscitation Device	EASYPUFF
Infant Incubator	KI-1000 NEOCARE NI-1000 KI-900
Infant Transport Incubator	KT-1000 NT-1000
Skin Probe	-

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

17 May 2021, Istanbul, Turkey