



EC CERTIFICATE

Phoenix Medical Systems (P) Ltd

DP 42, SIDCO INDUSTRIAL ESTATE
THIRUMUDIVAKKAM
CHENNAI, TN 600044
INDIA

Full Quality Assurance System Approval Certificate

Annex II, section 3 of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Design and manufacture of neonatal and infant radiant warmers, infant phototherapy units, nasal CPAP units, resuscitation system and baby incubators

Device Classification:

Ila and IIb

Device Descriptions:

Neonatal and infant radiant warmers, Infant phototherapy unit, nasal CPAP units, resuscitation system and baby incubators

Model Type:

Please refer to Attachment 1

We hereby declare that an examination of the full quality assurance system has been carried out per report 11230775, following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with (1) attachment listing model numbers.

File Number A11805
Certificate No. 645.151115

Cycle Start Date 09 November 2014
Effective Date 15 November 2016
Expiry Date 08 November 2017

Authorised by

Anwen E. Evans
Certification Manager

For and on Behalf of UL International (UK) Ltd

Notified Body

0843

00-NB-F0413

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom



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Attachment 1 of 1

The products detailed below are covered under the scope of this certificate

Product Family	Product Name	Model/Type	Classification
Neonatal and Infant Radiant Warmers	Neonatal Warmer Care System	NWC 100	IIb
	Infant Radiant Warmer	NWS 100 & NWS 101	IIb
	Wall Mounted Radiant Warmer	WMW 100	IIb
	Comprehensive Infant Care Centre	CIC 101	IIb
	Open Care Warmer	OCW 100	IIb
Infant Phototherapy Unit	CFL Phototherapy Unit	CFL 101	IIa
	Brilliance Phototherapy Unit	Brilliance, Brilliance Bottom	IIa
		Brilliance Pro	IIa
	LED Phototherapy Unit	LED PT 100, LED PT Bottom	IIa
Infant Airway Pressure Units	Nasal Continuous Positive Airway Pressure Unit	nCPAP 300 & nCPAP 200	IIb
Neonatal Resuscitation System	Neonatal Resuscitation Care System	NRC100	IIb
Baby incubator	Neonatal intensive care incubator	INC 200	IIb

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