



EC CERTIFICATE

Pluss Advanced Technologies Pvt. Ltd

610-A Udyog Vihar Phase V
Gurgaon, Haryana, 122016
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 non-electronic phase-change material-based cooling device for neonates

Device Classification:

Class IIb

Device Descriptions:

Medical device for cooling of neonates

Model Type:

MiraCradle™- Neonate Cooler

File Number	A28301	Cycle Start Date	12 May 2016
Certificate No.	796.150512	Effective Date	12 May 2016
		Expiry Date	11 August 2018

Authorised by

Anwen E. Evans
Certification Manager

For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per report 10645558, 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.

Notified Body

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