



# EC CERTIFICATE

## Skarray Technologies PVT Ltd

No. 15-17, Hebbal Industrial Area,  
Mysore, KA 570016  
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, patient monitoring systems, respiratory management systems, cardiac defibrillator/monitor and accessories**

Device Classification:

**Class IIa and IIb**

Device Descriptions:

**Patient Monitoring Systems, Patient Monitoring System Accessories, Respiratory Management systems, cardiac defibrillator/monitor**

Model Type:

**Please refer to Attachment 1**

Additional Manufacturing Site:

**Plot #360 KIADB Industrial Area, Hebbal, Mysore, Karnataka, 570018, India.**

File Number A17728  
Certificate No. 689.170718

Cycle Start Date 05 May 2016  
Effective Date 18 July 2017  
Expiry Date 11 May 2019

Authorised by

**Itoro Udofia  
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 11394222, 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.**

**Notified Body**

**0843**

MDD A2 S3 FQ

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	Model/Type	Classification
Patient Monitoring Systems	Star 90	Class IIb
	Comet Plus	Class IIb
	Star 60	Class IIb
	SpotSkan	Class IIa
	Star 65	Class IIb
Patient Monitoring Systems Accessories	AGM 55	Class IIb
Respiratory Management System	Athena 500i	Class IIb
	SkanRespiro	Class IIb
	SkanRespiro Plus	Class IIb
Portable External Defibrillator	SkanRevive	Class IIb
	CardiAid pro	Class IIb

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