



CERTIFICATE

EC Certificate No. 1434-MDD-389/2021

**Full Quality Assurance System
Directive 93/42/EEC concerning medical devices**

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Skanray Technologies Limited

**Plot # 15-17, Hebbal Industrial Area,
Mysore, Karnataka 570016 INDIA**

for the design, manufacture and final inspection of medical devices, class: Class IIb

**Patient monitoring systems, respiratory management
systems, cardiac defibrillator/monitor and accessories**

The list of medical devices covered by this certificate is provided in the Annex 1

**complies with requirements of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law, as evidenced by the audit conducted by the PCBC**

Validity of the Certificate: from 24.05.2021 to 27.05.2024

The date of issue of the Certificate: 24.05.2021

The date of the first issue of the Certificate: 29.08.2019



Issued under the Contract No. MD-84/2021
Application No: 541/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021
Module H2/3/4/5
FBM-26-E_9

Vice-President



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-389/2021

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Patient Monitoring Systems	Patient Monitoring Systems	Star 60-TruSKAN S500
		Star 60-TruSKAN S600
		Comet Plus
		Star 90
		Star 65
Portable External Defibrillator	Portable External Defibrillator	SkandRevive
		CardiAid pro
		Skandrevive+
		CardiAid Pro+
Respiratory Management System	Anesthetic Workstations	Athena 500i
		SkandSiesta
	Intensive Care Ventilators	SkandRespiro
		SkandRespiro Plus



Issued under the Contract No. MD-84/2021
Application No: 541/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021

Vice-President