

EC Certificate No. 1434-MDD-390/2021

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

Dental X-ray and diagnostic X-ray systems

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

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Issued under the Contract No. MD-84/2021 Application No: 542/2021 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-390/2021

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
C-Arm X-Ray	Mobile Surgical C Arm	SKAN C
High Frequency Dental X-Ray Systems	INTRA SKAN DC	INTRASKAN DC
High Frequency Diagnostic X-Ray Systems	Fixed X-ray	SKANRAD 400
	Mobile X-Ray	SKANMOBILE
		SKANMOBILE-T
		MicroSKAN
		MicroSKAN Ion
		SKANMOBILE DR



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Vice-President