



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 dental x-ray and diagnostic mobile x-ray systems

Device Classification:

Class IIb

Device Descriptions:

High-frequency intra-oral x-ray system for dental purposes and mobile diagnostic x-ray systems

Model Type:

Please refer to Attachment 1

File Number	A17728	Cycle Start Date	05 May 2016
Certificate No.	672.170724	Effective Date	24 Jul 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 11762447, 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



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Attachment 1 of 1

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

Product Family	Product Sub-Group	Model/Type	Classification
High Frequency Dental X-Ray system	INTRA SKAN DC	INTRA SKAN DC with 0.8 Focal Spot	Class IIb
		INTRA SKAN DC with 0.5 Focal Spot	Class IIb
		INTRA SKAN DC with 0.4 Focal Spot	Class IIb
High Frequency Diagnostic X-ray system	Mobile X-Ray	SKANMOBILE	Class IIb
		SKANMOBILE Digi	Class IIb
		SKANMOBILE-T	Class IIb
		MicroSKAN	Class IIb
		MicroSKAN Ion	Class IIb
C-Arm X-Ray	Mobile Surgical C-Arm	SKAN-C Mobile C-Arm X-Ray System	Class IIb

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