



CERTIFICATE OF REGISTRATION

Skанray Technologies Limited

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

Facility ID: F003310

UL Medical Regulatory Services of UL LLC®(UL) issues this certificate to the Firm named above, after auditing the Firm’s quality management system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

Design, development, manufacture, installation and servicing of diagnostic X-ray equipment, and digital imaging systems.

Design, development, manufacturing, installation and servicing of ECG equipment, defibrillators, surgical diathermy devices, anesthesia delivery systems, ventilators, multi parameter patient monitoring equipment.

Contract manufacturing of multi parameter patient monitors, automated external defibrillators.

Manufacture, installation and servicing of syringe pumps and infusion pumps.

With additional locations listed on Addendum: 1



Authorized by

Paul Hilgeman
Director & Global Industry Leader, Medical
CMIT – Medical Regulatory



Check Certificate Status:
[here](#)

| | | | |
|--------------------|--------------|------------------|--------------|
| File Number | A17728 | Cycle Start Date | May 12, 2023 |
| Certificate Number | 1887.230512 | Effective Date | May 12, 2023 |
| Initial Issue Date | May 12, 2019 | Expiry Date | May 11, 2025 |

This quality system registration is included in UL’s Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC. Certificates may be verified by visiting the Online Certifications Directory on UL.com.



**UL Medical and Regulatory
Services UL, LLC is an
MDSAP Recognized
Auditing Organization**

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA



CERTIFICATE OF REGISTRATION

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Addendum 1

1-1

Facility ID: **F003310**

Skанray Technologies Limited
Plot #15-17, Hebbal Industrial Area
Mysore, Karnataka 570016 INDIA

Performing: Management, regulatory affairs, design, development, manufacture, installation and servicing of diagnostic X-ray equipment, and digital imaging systems.

Design, development, installation and servicing of ECG equipment, defibrillators, surgical diathermy devices, anesthesia delivery systems, ventilators, multi patient monitoring equipment and accessories.

2-1

Facility ID: **F003367**

Skанray Technologies Limited
Plot #360, KIADB Industrial Area, Hebbal,
Mysore, Karnataka 570 018 INDIA

Performing: Management, regulatory affairs, design, development, manufacture, installation and servicing of ECG equipment, defibrillators, surgical diathermy devices, anesthesia delivery systems, ventilators, multi patient monitoring equipment and accessories;

Contract manufacture of multi parameter patient monitors, automated external defibrillators;

Virtual manufacture, installation and servicing of syringe pumps, infusion pumps;

Design, development, manufacture, installation and servicing of diagnostic x-ray equipment, digital imaging systems.

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Additional Regulatory Requirements

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

United States:

- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)

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