

Certificate of Registration

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A17728

Initial issue date

2019-05-12

Cycle start date

2025-05-12

Effective date

2025-05-12

Expiry date

2028-05-11

**Skanray Technologies Limited**

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

Facility ID: F003310

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016**EN ISO 13485:2016/A11:2021**

with additional regulatory requirements listed on the 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.

Certificate with Addendum(s) totals 3 pages.

Authorized by:

A handwritten signature in black ink, appearing to read 'P. Daysh'.

Paul Daysh
Operations manager – Medical Regulatory



Check certificate status: [here](#)

This quality system registration is included in UL's Product iQ directory and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown. By issuance of this certificate, the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferrable and remains the property of UL Solutions.

**UL LLC, UL Solutions medical regulatory services
is an MDSAP Recognized Auditing Organization**

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

Addendum 1

Site	Company Name	Location	Performing
1-1	Skanray Technologies Limited	Plot #15-17 Hebbal Industrial Area Mysore Karnataka 570016 INDIA Facility ID: F003310	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	Skanray Technologies Limited	Plot #360 KIADB Industrial Area Hebbal, Mysore Karnataka 570 018 INDIA Facility ID: F003367	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.

Additional Regulatory Requirements

Skandray Technologies Limited

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

Facility ID: F003310

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)