

Certificate US20/819943960

The quality management system of

LifeLine Software, Inc.

102 N College Ave suite 1014, Tyler, TX, 75702-7287, United States Of America

Facility number: F003645

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Canada: Medical Device Regulations SOR/98-282, Part 1

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

Design, development, manufacture and service of independent radiation dose verification software.

This certificate is valid from Effective date 2023-04-26 until Expiry date 2026-01-16 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 2020-06-17



Authorised by
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Head of Notified Body 1639

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.



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