Certificate US19/81841364

The quality management system of

Opti Medical Systems, Inc.

235 Hembree Park Drive, Suite 200, Roswell, GA, 30076, United States Of America
Facility number: F003086

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
Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021 – Field Actions; RDC ANVISA n. 67/2009 - Vigilance
Canada: Medical Device Regulations (SOR/98-282), Part 1 - General
Japan: Japan PMD Act (as applicable), MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 60 (2021)
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, manufacturing (including contract manufacturing), servicing and distribution of in-vitro diagnostic devices, test kits, reagents, analyzers and software used in diagnosis and management of blood analytes, blood components, blood gases, coagulation, clinical chemistry, and infectious disease.

This certificate is valid from Effective date 2025-01-23 until Expiry date 2028-01-23 and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 2019-01-24

L. Henderson

Authorised by

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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.