



Certificate Number US19/81841364

The quality management system of

# Opti Medical Systems, Inc.

235 Hembree Park Drive, Roswell, GA, 30076 United States

Facility identification number : F003086

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

## MDSAP(ISO 13485:2016)

**Australia:**  
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure (including design)

**Brazil:**  
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 / RDC ANVISA n. 67/2009

**Canada:**  
Medical Devices Regulations – Part 1 SOR 98/282

**Japan:**  
MHLW Ministerial Ordinance 169, Article 4 to Article 68 / PMD Act

**United States:**  
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

**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: 2022-01-24 until Expiry Date: 2025-01-23  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2024-12-06

Issue 2. Certified since 2019-01-24

Authorised by LHenderson  
Business Manager

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