



Certificate Number US19/81841364

The quality management system of

Opti Medical Systems, Inc.

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

Dun & Bradstreet D-U-N-S identification number: 80-145-8279

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 and clinical chemistry.

This certificate is valid from
Effective Date: 2019-01-24 until Expiry Date: 2022-01-23
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2021-12-06
Issue 1. Certified since 2019-01-24

Authorised by J Hall
Business Manager

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