

Certificate US22/00000011

The quality management system of

Medica Holdings, LLC

5200 Meadows Road, Suite 150, Lake Oswego, Oregon 97035

Facility Identification Number: F000284

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)

Canada:

Medical Devices Regulations – Part 1 SOR 98/282

Japan:

MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68
Japan PMD Act

United States:

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 and devices

Design, manufacture, and distribution of spirometers, nasal atomizers, and sterile and non-sterile single-use intubating stylets for the areas of anaesthesia and respiratory care.

This certificate is valid from Effective Date: 07 July 2022 until Expiry Date: 10 August 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 09 June 2023
Issue 1. Certified since 07 July 2022.

Authorised by

L. Henderson

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