Certificate US19/819943345

The quality management system of

Hurricane Medical

5315 Lena Road, Bradenton, FL, 34211-9442, United States Of America

Facility Identification Number: F003949

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 - Full Quality Assurance System
Brazil Jurisdictions
RDC ANVISA n. 16/2013 - Good Manufacturing Practices
RDC ANVISA n. 23/2012
RDC ANVISA n. 67/2009 - Vigilance
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 sterile and non-sterile ophthalmic cannula, cystotomes, needles, eye shields, ophthalmic sponges, fluid filters, glides, handled ophthalmic Instruments, incise film, and marker pads and pens for the area of ophthalmology.

This certificate is valid from Effective Date: 29 July 2022 until Expiry Date: 24 July 2025
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 24 July 2025

Issue 2. Certified since 30 August 2019.

Authorised by

L. Henderson

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