

Certificate US19/819943345

The quality management system of

Hurricane Medical

SGS

5315 Lena Road, Bradenton, FL 34211, United States of America
Facility number: F003949

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: 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, 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 2025-07-24 until Expiry date 2028-07-24 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 2019-08-30

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.



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