

Certificate Number US19/819943345

The management system of

Hurricane Medical

5315 Lena Road, Bradenton, FL, 34211, United States
Dun & Bradstreet D-U-N-S identification number : 09-337-7724

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]
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 / 21 CFR 821

For the following activities and devices

See second page for the scope.

The certificate is valid from
Effective Date: 2019-08-30 until Expiry Date: 2022-08-29
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2022-07-19
Issue 1. Certified since 2019-08-30



Authorised by J Hall
Business Manager



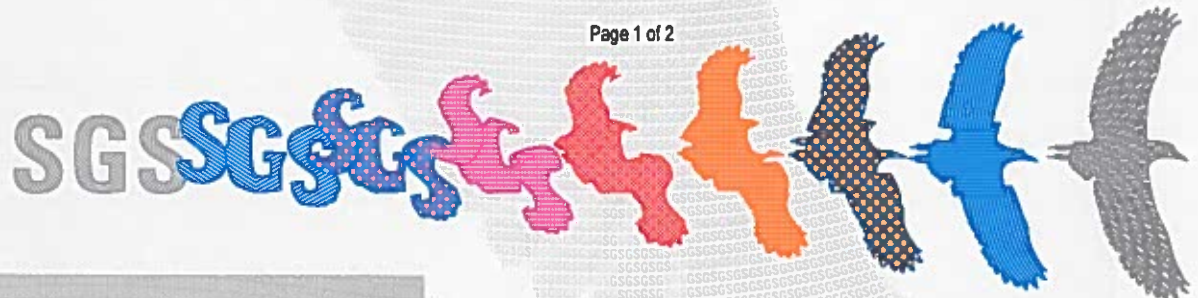
Jonathan M. Hall

SGS United Kingdom Ltd
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

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MDSAP M2

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Hurricane Medical MDSAP (ISO 13485:2016)

Issue 1



Detailed scope

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.

USA:

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.

Japan:

Design, manufacture and distribution of sterile and non-sterile ophthalmic cannula, cystotomes, and needles for the area of ophthalmology.

Australia:

Design, manufacture and distribution of sterile and non-sterile ophthalmic cannula, cystotomes, needles, eye shields, ophthalmic sponges, handled ophthalmic instruments, and marker pads and pens for the area of ophthalmology.



Canada:

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.

