EC Certificate Production Quality Assurance System: Certificate US99/50930

The management system of

# Hurricane Medical

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

has been assessed and certified as meeting the requirements of

# Directive 93/42/EEC

**on medical devices, Annex V**

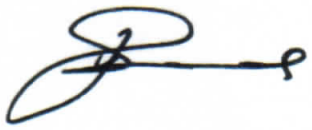
For the following products

**The scope of registration appears on page 2 of this certificate**

This certificate is valid from 19 March 2018 until 27 September 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 25 September 2020
Issue 12. Certified since 27 September 1999

Certification is based on reports numbered WW/MC 200452

Authorised by



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# Hurricane Medical

## Directive 93/42/EEC

**on medical devices, Annex V**

Issue 12

Detailed scope

**Sterile ophthalmic cannula, cystotomes, anesthesia needles, ophthalmic spears, sticks wicks and wipes, micron fluid filters, ophthalmic surgical instruments (lens manipulators & nucleaus choppers), and glides.**

**Class 1 Sterile "Sterility aspects only - Restricted to the aspects of manufacture concerned with securing andmaintaining sterile conditions":**

**Marker pads used to mark the eye prior to an ophthalmic surgical procedure. Marking pens used to mark the eye or surrounding skin prior to an ophthalmic surgical procedure.**

**Corneal light shields and LASIK shields used to protect the eye from light and tissue dehydration during an ophthalmic surgical procedure**

**Incise Film used to isolate the skin and hair from the ophthalmic surgical site prior to surgery.**

**Eye shield used to protect the eye from external trauma after an ophthalmic surgical procedure.**

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.