

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

### Annex V

**Sterile and non-sterile ophthalmic cannula, cystotomes, ophthalmic needles, eye shields, wicks and wipes, fluid filters, ophthalmic surgical instruments, including spears, glides and incise film.**

**Class I Sterile: "Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining 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.**

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.

This certificate is valid from 16 March 2015 until 27 September 2019 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 26 September 2017  
Issue 9. Certified since 27 September 1999

Certification is based on reports numbered WW/ME 200452

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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