

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 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 27 September 1999
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/MC/ 200452

Authorised by

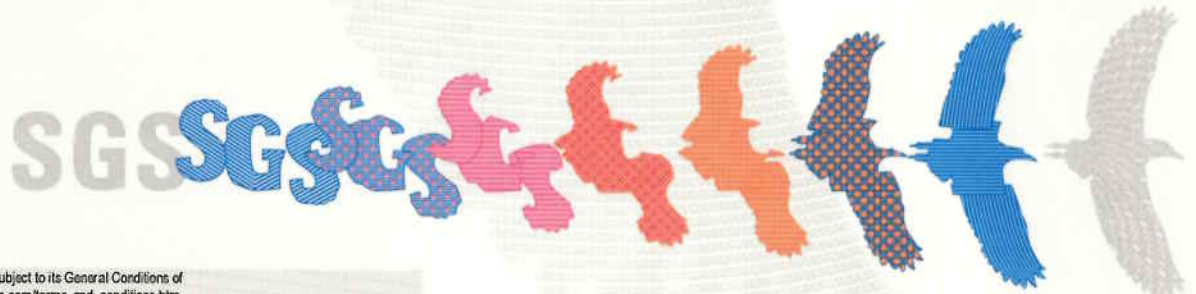
Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5008 - Certificate CE1639 AnnexV_EN rev. 01

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Hurricane Medical

Directive 93/42/EEC

on medical devices, Annex V

Issue 1

Detailed scope

Non-sterile and sterile ophthalmic devices including: cystotomes, anesthesia needles, ophthalmic glides, ophthalmic reusable surgical instruments (lens manipulators & nucleus choppers), ophthalmic cannula, micron fluid filters, ophthalmic spears, sticks, wicks, wipes

Annex V 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.**

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 III medical device(s), a valid EC Design Examination Certificate according to Annex V is a mandatory requirement for each device in addition to this certificate to place that device on the market.

