

EC-Certificate

(full quality assurance system)
according to annex II, section 3 of
Medical Devices Directive 93/42/EEC

It is herewith confirmed by

EUROCAT Institute for Certification and Testing

Quarat[®] Center * Wittichstrasse 2
64295 Darmstadt * Germany
Identification No. 0535,
in its function as Notified Body,

that the manufacturer

FLUORON GmbH

**Magirus-Deutz-Str. 10
89077 Ulm, Germany**

concerning the medical device
(products/variants specified in enclosure)
fulfils the requirements according
to Annex II, section 3,
Medical Devices Directive 93/42/EEC.

The manufacturer has established a quality
assurance system for the design, production
and final inspection of specified devices.

The enclosure is part of this certificate
and contains 1 page.

Date of initial registration:
23 October 2003.

Based on the periodical surveillance the
certificate is valid until 30 May 2011.

Report No.: BQM09259HU01
Certificate No.: **CQ093001-II**

CE 0535



Accredited by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-914.99.04

Darmstadt, 27 October 2009


Certification Body



Enclosure of EC-Certificate

(full quality assurance system)

according to annex II, section 3, Medical Devices Directive 93/42/EEC

Certificate No.: CQ093001-II

Medical devices of the manufacturer:

FLUORON GmbH

**Magirus-Deutz-Str. 10
89077 Ulm, Germany**

Name of product	Variant	Item	UMDNS	Class
Densiron [®] 68				II b
Densiron [®] 68 LV				II b
Blueron [®]				II a
Vitreous Substitute F6H8 [®]				II b
Siluron [®] 1000				II b
Siluron [®] 2000				II b
Siluron [®] 5000				II b
F-Decalin				II a
F-Octane				II a
F-Decalin ^{Plus}				II a
F-Octane ^{Plus}				II a
F-Octane ^{Light}				II a
Semifluoran F6H6				II a
Brilliant Peel [®]				II a

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EUROCAT Institute for Certification and Testing GmbH, 64295 Darmstadt, Germany,

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