

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 575554**
Issued To: **Fluoron GmbH**
Magirus-Deutz-Str. 10
89077 Ulm
Germany

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **27 June 2016**

Date: **27 June 2016**

Expiry Date: **10 April 2021**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 575554

Certificate Scope:

Design, development and manufacture of sterile silicone oils, perfluorocarbons and semi-fluorinated alkanes for use as liquid, intraocular tamponades, gas-based intraocular tamponades, semi-fluorinated liquid vitreous substitutes, semi-fluorinated alkane washout solutions and aqueous staining solutions for ophthalmological use.

Design, Entwicklung und Herstellung von sterilen Silikonölen, Perfluorcarbonen und semifluorierten Alkanen als flüssige, intraokulare Tamponaden, gasförmige, intraokulare Tamponaden, semifluorierte flüssiger Glaskörper-Ersatz, semifluorierte Alkane als Spüllösungen und wässrigen Färbelösungen für die Ophthalmologie.

First Issued: **27 June 2016**Date: **27 June 2016**Expiry Date: **10 April 2021**

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