By Royal Charter

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 2797):

Albert Roossien, Regulatory Lead

First Issued: **2016-06-27** Date: **2019-03-05** Expiry Date: **2021-04-10**

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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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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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, semifluorierter flüssiger Glaskörper-Ersatz, semifluorierte Alkane als Spüllösungen und wässrigen Färbelösungen für die Ophthalmologie.

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Supplementary Information to CE 575554

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Number	Device Name	Intended purpose per IFU
Class IIb		
MD 0105	silicone oil based long-term tamponades	implantable, postoperative eye tamponade
MD 0105	silicone oil/alkane mix as long-term tamponades	implantable, postoperative eye tamponade
MD 0105	perfluorinated gases as long-term tamponade	implantable, postoperative eye tamponade
MD 0105	semi-fluorinated alkane as long-term tamponades	implantable, postoperative eye tamponade
Class IIa		
MD 0105	perfluorinated alkanes as intraoperative tamponade	--
MD 0105	semi-fluorinated alkane as wash-out	--
MD 0105	aqueous solution for staining	--

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