

# 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:

**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 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 Alkane als Spüllösungen und wässrigen Färbelösungen für die Ophthalmologie.**

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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-06-27**

Date: **2021-04-08**

Expiry Date: **2024-05-26**

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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.

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## Supplementary Information to CE 575554

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**Fluoron GmbH  
Magirus-Deutz-Str. 10  
89077 Ulm  
Germany**

| Number           | Device Name  | Intended purpose per IFU                 |
|------------------|--|--|
| <b>Class IIb</b> |  |  |
| 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 |
| <b>Class IIa</b> |  |  |
| 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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