

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

Holds Certificate Number:

MD 575553

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-06-27

Latest Revision Date: 2018-12-06

Effective Date: 2018-12-06

Expiry Date: 2021-12-05

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Certificate No: **MD 575553**

Registered 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. Contract manufacturing according to customer specifications.

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. Lohnherstellung nach Kundenvorgaben.



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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