By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

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 13485:2003 & EN ISO 13485:2012 for the following scope:

Please see scope page.

For and on behalf of BSI:

Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 27/06/2016
Latest Revision Date: 27/06/2016

Effective Date: 27/06/2016
Expiry Date: 27/02/2020

...making excellence a habit.™

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

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

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