

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:

Design, development and manufacture of sterile silicone oils, perfluorocarbons and semi-fluorinated alkanes for use as liquid, intraocular endotamponades and 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 und gasförmige, intraokulare Tamponaden, semifluorierte Alkane als Spüllösungen und wässrigen Färbelösungen für die Ophthalmologie.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2016-06-27

Latest Revision Date: 2023-05-11

Effective Date: 2023-05-14

Expiry Date: 2026-05-13



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