By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Facility ID Number: F000187

Holds Certificate No: **MDSAP 692797**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Design, development and manufacture of sterile silicone oils, perfluorocarbons and semifluorinated alkanes for use as liquid, intraocular endotamponades and gas-based intraocular tamponades and vitreous substitutes, and aqueous staining solutions for the area of ophthalmology.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-05-14 Effective Date: 2023-05-14 Expiry Date: 2026-05-13

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

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