EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 754100 R000

Manufacturer: Rayner Intraocular Lenses Limited

Address:
The Ridley Innovation Centre
10 Dominion Way
Worthing
West Sussex
BN14 8AQ
United Kingdom

Single Registration Number: GB-MF-000018056

EU Authorised Representative: Rayner Surgical GmbH

Address:
Rudower Chaussee 9
D-12489 Berlin
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-09-06**

Current Issue Date: **2024-03-20**

Starting Validity Date: **2024-03-20**

Expiry Date: **2027-09-05**

...making excellence a habit.™

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 754100 R000

Device Schedule: Class III and Class IIb devices

Class IIb, Implantable	Intended purpose
RayOne Intraocular Lenses	See MDR 754108
RayOne Hydrophobic Intraocular Lenses	See MDR 754111
Sulcoflex Sulcus Intraocular Lenses	See MDR 754110

Class IIb	Intended purpose
Methylvisc & Ophteis range of ophthalmic viscoelastic devices	Maintains anterior chamber depth during surgery and protects intraocular tissue

First Issue Date: **2022-09-06**

Current Issue Date: **2024-03-20**

Starting Validity Date: **2024-03-20**

Expiry Date: **2027-09-05**

...making excellence a habit.™

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 754100 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-09-06	3491302	Issued
2023-09-14	3886143	Supplemented – Addition of Hydrophobic Devices Addition of Ophthalmic Viscoelastic Devices
Current	30112587	Supplemented – Addition of Sulcus Intraocular Lenses

First Issue Date: **2022-09-06**

Current Issue Date: **2024-03-20**

Starting Validity Date: **2024-03-20**

Expiry Date: **2027-09-05**

...making excellence a habit.™