

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

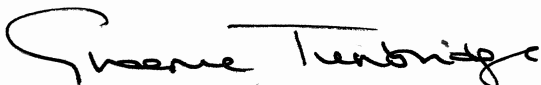
Address:

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 and Class IIb implantable devices an 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: **2022-09-06**

Starting Validity Date: **2022-09-06**

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

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Device Schedule: Class III and Class IIb devices

Class IIb, Implantable	Intended purpose
RayOne Intraocular Lenses	See MDR 754108



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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
Current	3491302	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 754100 R000

Date: 2022-09-06

Critical Subcontractor/Crucial Supplier	Service(s) supplied
AST Products, Inc. 9 Linnell Circle Billerica Massachusetts 01821 USA	Manufacture

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