EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 754108 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 assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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:

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Intended purpose** (as per the IFU)	**Risk Classification**	**Basic UDI-DI**
RayOne Spheric	RAO 100C	MDN 1104	Rayner IOLs are indicated for the visual correction of aphakia in patients in whom a cataractous lens has been removed by phacoemulsification or extracapsular cataract extraction. These devices are intended to be placed in the capsular bag.	Class IIb Implantable -non-WET	0502986 7004087
RayOne EMV	RAO 200E	MDN 1104	Additionally, aspheric models are aberration neutral and therefore do not add to the spherical aberration of the eye.	Class IIb Implantable -non-WET	0502986 7004254
RayOne Aspheric	RAO 600C	MDN 1104	Additionally, aspheric models are aberration neutral and therefore do not add to the spherical aberration of the eye.	Class IIb Implantable -non-WET	0502986 7004070
RayOne Toric	RAO 610T	MDN 1104	Additionally, Toric models are intended to provide adjustment to the astigmatism of the eye.	Class IIb Implantable -non-WET	0502986 7004094
RayOne Trifocal	RAO 603F	MDN 1104	Additionally, Trifocal models are intended to provide pseudo accommodation to the eye.	Class IIb Implantable -non-WET	0502986 7004100
RayOne Trifocal Toric	RAO 613Z	MDN 1104	Additionally, Toric models are intended to provide adjustment to the astigmatism of the eye. Trifocal models are intended to provide pseudo accommodation to the eye.	Class IIb Implantable -non-WET	0502986 7004117
RayOne EMV Toric	RAO 210T	MDN 1104	Additionally, Toric models are intended to provide adjustment to the astigmatism of the eye.	Class IIb Implantable -non-WET	0502986 7003912

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Additional Information:

RayOne Spheric
Spherical equivalent power at IOL plane, -10.0 to +8.0D and +30.0 to +34.0D in 1.0D Increments
+8.5 to +29.5D in 0.5D Increments
RayOne EMV
Spherical equivalent power at IOL plane, +10.0 to +30.0D in 0.5D Increments
RayOne Aspheric
Spherical equivalent power at IOL plane, -10.0 to +8.0D and +30.0 to +34.0D in 1.0D Increments
+8.5 to +29.5D in 0.5D Increments
RayOne Toric
Spherical equivalent power at IOL plane, -9.5 to +34.5D in 0.5D Increments,
Cylinder power at IOL plane +1.0 to +11.0 D in 0.5D Increments
RayOne Trifocal
Spherical equivalent power at IOL plane, 0.0 to +30.0D in 0.5D Increments,
Additional power at IOL plane of +3.5D Near and +1.75D Intermediate
RayOne Trifocal Toric
Spherical equivalent power at IOL plane, +6.0 to +30.0 D in 0.5D Increments,
Cylinder power at IOL plane +0.75 to +4.5D in 0.75D Increments,
Additional power at IOL plane of +3.5D Near and +1.75D Intermediate
RayOne EMV Toric
Spherical equivalent power at IOL plane, +10.0 to +25.0D in 0.5D Increments,
Cylinder power at IOL plane +0.75 to +4.5 D in 0.75D Increments

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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	3491313	Issued

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