

# 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

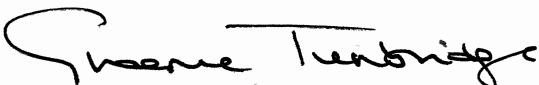
**Address:**

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 Global Regulatory & Quality

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

Current Issue Date: **2024-07-17**

Starting Validity Date: **2024-07-17**

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	5029867RAO100CRT
RayOne EMV	RAO 200E	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	5029867RAO200ES6
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	5029867RAO600CSW
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	5029867RAO610TU5
RayOne Trifocal	RAO 603F	MDN 1104	Additionally, Trifocal models are intended to provide pseudo accommodation to the eye.	Class IIb Implantable - non-WET	5029867RAO603FTD

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Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended Purpose (as per the IFU)	Risk Classification	Basic UDI-DI
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	5029867RAO613ZUS
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	5029867RAO210TT9
RayOne Galaxy	RAO 605G	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	502867RAO605GTM
RayOne Galaxy Toric	RAO 615X	MDN 1104	Additionally, Toric models are intended to provide adjustment to the astigmatism of the eye.	Class IIb Implantable -non-WET	5029867RAO615XUU

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### Additional Information:

#### RayOne Spheric

Spherical equivalent power at IOL plane, -10.0 to +8.0 D and +30.0 to +34.0 D in 1.0 D Increments  
+8.5 to +29.5 D in 0.5 D Increments

#### RayOne EMV

Spherical equivalent power at IOL plane, +10.0 to +30.0 D in 0.5 D Increments

#### RayOne Aspheric

Spherical equivalent power at IOL plane, -10.0 to +8.0 D and +30.0 to +34.0 D in 1.0 D Increments  
+8.5 to +29.5 D in 0.5 D Increments

#### RayOne Toric

Spherical equivalent power at IOL plane, -9.5 to +34.5 D in 0.5 D Increments,  
Cylinder power at IOL plane +1.0 to +11.0 D in 0.5 D Increments

#### RayOne Trifocal

Spherical equivalent power at IOL plane, 0.0 to +30.0 D in 0.5 D Increments,  
Additional power at IOL plane of +3.5 D Near and +1.75 D Intermediate

#### RayOne Trifocal Toric

Spherical equivalent power at IOL plane, +6.0 to +30.0 D in 0.5 D Increments,  
Cylinder power at IOL plane +0.75 to +4.5 D in 0.75 D Increments,  
Additional power at IOL plane of +3.5 D Near and +1.75 D Intermediate

#### RayOne EMV Toric

Spherical equivalent power at IOL plane, +10.0 to +25.0 D in 0.5 D Increments,  
Cylinder power at IOL plane +0.75 to +4.5 D in 0.75 D Increments

#### RayOne Galaxy

Spherical equivalent power at IOL plane, +5.0 to +30.0 D in 0.5 D Increments  
Additional power at IOL plane of +3.0 D Near and +1.5 D Intermediate

#### RayOne Galaxy Toric

Spherical equivalent power at IOL plane, +6.0 to +30.0 D in 0.5 D Increments,  
Cylinder power at IOL plane +0.75 to +4.5 D in 0.75 D Increments  
Additional power at IOL plane of +3.0 D Near and +1.5 D Intermediate

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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
2022-09-06	3491313	Issued
2023-03-24	3874274	Amended – correction of intended purpose wording for RayOne EMV (RAO200E)
2024-03-25	30119821	Amended – Updates of Basic-UDI-DI to GMN format
Current	30160306	Supplemented – Addition of RayOne Galaxy and RayOne Galaxy Toric



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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.