

Manufacturer

Rayner Intraocular Lenses Limited
The Ridley Innovation Centre
10 Dominion Way, Worthing, West Sussex,
BN14 8AQ,
United Kingdom.

SRN: GB-MF-000018056

EC Representative

RAYNER SURGICAL GmbH
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D-12489 Berlin
Deutschland

SRN: DE-AR-000015767

Friday, 02 August 2024

Ref: (2024-08-02) MDR DoC 600 v5

EC DECLARATION OF CONFORMITY

Preloaded Hydrophilic IOL Injection System

Rayner Intraocular Lenses Limited is exclusively responsible for this Declaration of Conformity. The conformity assessment complies with MDR Annex IX Conformity Assessment Based On A Quality Management System And On Assessment Of Technical Documents.

Rayner Intraocular Lenses Limited Preloaded IOL Injection Systems (listed below), each comprise a single intraocular lens (IOL) within a single intraocular lens injector.

Rayner Intraocular Lenses Limited declares that the IOLs of class IIb (MDR, Annex VIII, rule 8), and injectors of class IIa, (MDR, Annex VIII, rule 6), used in these systems are:

- In conformity with the General Safety and Performance Requirements of the European Council Medical Device Regulation (EU) 2017/745.
- Subject to the procedure set out in Annex IV of the Regulation under the supervision of Notified Body Number 2797, BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands (see BSI certificate MDR 754100 R000 and MDR 754108 R000).

Rayner Intraocular Lenses Limited declares that the systems are class IIb.

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.

The Devices

Product Name	Product Code	Variants	Basic UDI-DI
RayOne Spheric	RAO100C	Power Range -10.0 to +8.0 D (1.0 D increments) +8.5 to +29.5 D (0.5 D increments) +30.0 to +34.0 D (1.0 D increments)	5029867RAO100CRT
RayOne EMV	RAO200E	Power Range +10.0 to +30.0 D (0.5 D increments)	5029867RAO200ES6
RayOne Aspheric	RAO600C	Power Range -10.0 to +8.0 D (1.0 D increments) +8.5 to +29.5 D (0.5 D increments) +30.0 to +34.0 D (1.0 D increments)	5029867RAO600CSW



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Product Name	Product Code	Variants	Basic UDI-DI
RayOne Toric	RAO610T	Spherical Equivalence -9.5 to +34.5 D (0.5 D increments) Cylinders +1.0 to +11.0 D (0.5 D increments)	5029867RAO610TU5
RayOne Trifocal	RAO603F	Sphere Power 0.0 to +30.0 D (0.5 D increments) Additions +3.5 D Near +1.75 D Intermediate	5029867RAO603FTD
RayOne Trifocal Toric	RAO613Z	Spherical Equivalence +6.0 to +30.0 D (0.5 D increments) Cylinders +0.75 to +4.5 D (0.75 D increments) Additions +3.5 D Near +1.75 D Intermediate	5029867RAO613ZUS
RayOne EMV Toric	RAO210T	Spherical Equivalence +10.0 to +25.0 D (0.5 D increments) Cylinders +0.75 to +4.5 D (0.75 D increments)	5029867RAO210TT9
RayOne Galaxy	RAO605G	Sphere Power +5.0 to +30.0 D (0.5 D increments) Additions +3.0 D Near +1.5 D Intermediate	5029867RAO605GTM
RayOne Galaxy Toric	RAO615X	Spherical Equivalence +6.0 to +30.0 D (0.5 D increments) Cylinders +0.75 to +4.5 D (0.75 D increments) Additions +3.0 D Near +1.5 D Intermediate	5029867RAO615XUU

Signed,



Daniel Peek (Aug 2, 2024 10:12 GMT+1)

Daniel Peek
 Director of Regulatory Affairs
 Signed at 10 Dominion Way, Worthing, West Sussex, BN14 8AQ, UK






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Final Audit Report

2024-08-02

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