

Rayner Intraocular Lenses Limited

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Ref: EC Declaration of Conformity - Preloaded (2019-03-07)

EC DECLARATION OF CONFORMITY

Preloaded IOL Injection System

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 (MDD, Annex IX, rule 8), and injectors of class IIa, (MDD, Annex IX, rule 6), used in these systems are:

- 1 In conformity with the essential requirements and provisions of the European Council Medical Device Directive 93/42/EEC (as amended), as transposed into UK legislation via Statutory Instrument (2002) № 618 and subsequent amendments (2003) № 1697, and (2008) № 2936.
- 2 Subject to the procedure set out in Annex II of the Directive under the supervision of Notified Body Number 2797, BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands (see BSI certificate CE 664780).

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

The Devices

- RayOne Spheric (Model RAO100C)
- RayOne Aspheric (Model RAO600C)
- RayOne Toric (Model RAO610T)
- RayOne Trifocal (Model RAO603F)
- RayOne Hydrophobic Aspheric (Model RAO800C)

Signed,



Daniel Peek
Head of Regulatory Affairs



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