



Rayner Intraocular Lenses Limited

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Ref: EC Declaration of Conformity - Family 11 (2019-03-07)

EC DECLARATION OF CONFORMITY

Intraocular Lenses with Single Use Injectors

Rayner Intraocular Lenses Limited Intraocular Lenses with Single Use Injectors (listed below), each comprise a single intraocular lens (IOL) together with 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) No 618 and subsequent amendments (2003) No 1697, and (2008) No 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 certificate CE 660380).

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

The Devices

- C-flex with Single Use Soft-Tipped Injector (Model 570C)
- C-flex with RaySert PLUS Injector (Model RSP570C)
- Superflex with Single Use Soft-Tipped Injector (Model 620H)
- C-flex Aspheric with Single Use Soft-Tipped Injector (Model 970C)
- C-flex Aspheric with RaySert PLUS Injector (Model RSP970C)
- Superflex Aspheric with Single Use Soft-Tipped Injector (Model 920H)
- Superflex Aspheric with RaySert PLUS Injector (Model RSP920H)
- T-flex Aspheric with Single Use Soft-Tipped Injector (Model 573T)
- T-flex Aspheric with Single Use Soft-Tipped Injector (Model 623T)
- M-flex with Single Use Soft-Tipped Injector (Model 580F)
- M-flex with Single Use Soft-Tipped Injector (Model 630F)

- M-flex with Single Use Soft-Tipped Injector (Model 630N)
- M-flex T with Single Use Soft-Tipped Injector (Model 588F)
- M-flex T with Single Use Soft-Tipped Injector (Model 638F)
- Sulcoflex Aspheric with Single Use Soft-Tipped Injector (Model 653L)
- Sulcoflex Toric with Single Use Soft-Tipped Injector (Model 653T)
- Sulcoflex Multifocal with Single Use Soft-Tipped Injector (Model 653F)
- Sulcoflex Multifocal Toric with Single Use Soft-Tipped Injector (Model 653Z)
- Sulcoflex Trifocal (Model IOL703F)

Signed,



Daniel Peek
Head of Regulatory Affairs



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