Rayner Intraocular Lenses Limited

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07 March 2019

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

EC DECLARATION OF CONFORMITY

Ophthalmic Viscosurgical Devices

Rayner Intraocular Lenses Limited ophthalmic viscosurgical devices (listed below) are supplied sterile in syringes with single use cannula.

Rayner Intraocular Lenses Limited declares that the ophthalmic viscoelastic devices of class IIb (MDD, Annex IX, rule 8) 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 660380).

Rayner Intraocular Lenses Limited declares that the ophthalmic viscosurgical devices are class IIb.

The Devices

- Methylvisc (Model R-MLV20)
- Ophteis Bio 1.6% (Model R-OPB16)
- Ophteis Bio 1.8% (Model R-OPB18)
- Ophteis Bio 3.0% (Model R-OPB30)
- Ophteis FR Pro (Model R-OPFR)

Signed,

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Daniel Peek
Head of Regulatory Affairs