

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 660380
Issued To: **Rayner Intraocular Lenses Limited**
The Ridley Innovation Centre
10 Dominion Way
Worthing
West Sussex
BN14 8AQ
United Kingdom

In respect of:

Design, manufacture and final inspection of sterile intraocular lenses with single use injectors, sterile single use injectors and ophthalmic viscoelastic devices

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2016-11-29**

Date: **2018-04-20**

Expiry Date: **2023-04-21**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Optimold Ltd 12 Golborne Enterprise Park Warrington WA3 3GR United Kingdom	Manufacture
Sterigenics UK Limited Cotes Park Estate Somercotes Alfreton DE55 4NJ United Kingdom	ETO Sterilization
VSY Biyoteknoloji ve İlaç Sanayi Anonim Sirketi Ataturk Mah Kamilsey Sok No. 4 Kucukbakkalkoy Atasehir Istanbul Turkey	Design ETO Sterilization Manufacture Moist Heat Sterilization

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
29 November 2016	8591715	First issue; transfer from another Notified Body.
03 November 2017	8789574	Removal of Rayner IOL Ltd, Hove as significant subcontractor.
19 December 2017	8873353	Extension to scope for ophthalmic viscoelastic devices. Addition of VSY as significant subcontractor.
Current	8923836	Renewal Addition of Optimold Ltd as significant subcontractor for manufacture