

EC Certificate - Full Quality Assurance System

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

No. **CE 615365**
Issued To: **SAV-IOL SA**
Falaises 74
2000 Neuchatel
Switzerland

In respect of:

Design, manufacture and final inspection of intraocular lenses

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-12-23**

Date: **2020-12-15**

Expiry Date: **2024-05-26**

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Page 1 of 2

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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Supplementary Information to CE 615365

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Number	Device Name	Intended purpose per IFU
Class IIb		
35658	EDEN	Implantable intraocular lens
35658	EDEN TORIC	Implantable intraocular lens
35658	LUCIDIS	Implantable intraocular lens
35658	LUCIDIS TORIC	Implantable intraocular lens
35658	HARMONIS	Implantable intraocular lens

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Page 2 of 2

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Certificate History

Certificate No: **CE 615365**
 Date: **2020-12-15**
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Date	Reference Number	Action
23 December 2015	8165103	First issue.
07 February 2019	8481764	Traceable to NB 0086.
Current	3328556	Certificate renewed and device table added

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Page 1 of 1

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