

EC Certificate - Full Quality Assurance System

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

No. CE 682489
Issued To: **AJL Ophthalmic SA**
Parque Tecnológico de Álava
Ferdinand Zeppelin 1
Miñano
Alava
01510
Spain

In respect of:

Design, development, and manufacture of intraocular lenses, intraocular viscoelastic solutions, ophthalmic dye solutions, scleral implants, palpebral implants, orbital sphere implants, ocular shields, perforated conformers, and symblepharon rings.

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):



Albert Roossien, Regulatory Lead

First Issued: **2019-02-13**

Date: **2019-02-27**

Expiry Date: **2023-10-13**

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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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Supplementary Information to CE 682489

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Number	Device Name	Intended purpose per IFU
Class IIb		
Intraocular lenses	AIALA DRY PRELOADED Intraocular lens	Lens replacement in the surgical correction of aphakia.
Intraocular lenses	AIALA DRY Intraocular lens	Lens replacement in the surgical correction of aphakia.
Intraocular lenses	AS-IOL Intraocular lens	Lens replacement in the surgical correction of aphakia.
Intraocular lenses	ORIOLE Intraocular lens	Lens replacement in the surgical correction of aphakia.
Intraocular Viscoelastic Solution	AJL VISC	Surgical aid in surgical procedures in the anterior segment of the eye, including cataract surgery.
Intraocular Viscoelastic Solution	AJL CELL	surgical aid in surgical procedures in the anterior segment of the eye, including cataract surgery.
Ophthalmic dye solutions	AJL BLUE	Stain membranes during cataract surgery
Ophthalmic dye solutions	AJL BBG	Stain membranes during retinal surgery.

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Scleral Implant	ESNOOPER V2000 Scleral Implant	Intended to create space for reabsorption and drainage of aqueous humor in patients with open-angle glaucoma
Scleral Implant	ESNOOPER Clip	Intended to create space for reabsorption and drainage of aqueous humor in patients with open-angle glaucoma
Palpebral Implant	ALOS Eyelid Implant, Platinum	Intended to treat functional defects of lagophthalmos.
Orbital implant	Oculfit Orbital Implant	Intended to fill the void resulting from an enucleated or eviscerated eye.
Class IIa		
Ocular Shield	AJL Eye Shield	---
Symblepharon Ring	AJL Perforated Conformer	---
Perforated Conformer	AJL Symblepharon ring	---

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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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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Art Lens Passeig De Gracia 117 Barcelona 08008 Spain	Manufacture
Taller De Joyeria Barcena San Francisco Javier 10 Vitoria Spain	Manufacture
Taller Joyeria Leza Badaia Kalea, 26 Vitoria-Gasteiz Araba 01012 Spain	Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
Current	8847653	First issue, transfer from another notified body. Certificate renewal.
13 February 2019	8868044	Traceable to NB 0086.

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