

EC Certificate

Full Quality Assurance System

Certificate No.:
11536-2017-CE-IBE-NA-PS Rev. 0.0

Project No.:
PRJC-58170-2008-PRC-ESP

Valid Until:
13 October 2018

This is to certify that the quality system of:

AJL OPHTHALMIC, S.A.

Parque Tecnológico de Álava
01510 Miñano
Spain

For design, production and final product inspection/testing of:

Ophthalmic Devices

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 30 October 2017



For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces the certificate 3795-2013-CE-IBE-NA Rev.1 (NB 0434), following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	2017-10-30

Products covered by this Certificate:

Product Description	Product Name	Class
Platinum Palpebral Implant GMDN: 18074	<ul style="list-style-type: none"> • Platinum Model P • Platinum Model PTH (thin) 	IIb
Intraocular Lens posterior chamber pseudophakic GMDN: 35658	<ul style="list-style-type: none"> • ORIOL (Yellow filter, Hydrophilic) <ul style="list-style-type: none"> ○ Models: LLY5502 ○ LLY6002 • ORIOL MAX (Yellow filter, Hydrophilic, 3 haptics) <ul style="list-style-type: none"> ○ Model: LLY360 	IIb
	<ul style="list-style-type: none"> • AIALA DRY (Hydrophobic) <ul style="list-style-type: none"> ○ LLHP60 (Yellow filter) ○ HP60 ○ LLASHP60 (Aspheric Yellow filter) ○ ASHP60 (Aspheric) ○ LLASHP60-PL (PRELOADED) ○ ASHP60-PL (PRELOADED) ○ LLHP60-PL (PRELOADED) ○ HP60-PL (PRELOADED) 	
	<ul style="list-style-type: none"> • AS-IOL (Aspheric, Hydrophilic) <ul style="list-style-type: none"> ○ LLASF60 (Yellow filter) ○ LLASY60 (Yellow filter) 	

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Intraocular Lens pseudophakic for Low Vision	<ul style="list-style-type: none"> • DM Plus (PMMA) Posterior chamber <ul style="list-style-type: none"> ○ Model: P501300 Anterior chamber (PMMA) <ul style="list-style-type: none"> ○ Models: A501300 ○ A501200 ○ A501100 	IIb
Intraocular Viscoelastic Solution	<ul style="list-style-type: none"> • AJL VISC (Sodium Hyaluronate) <ul style="list-style-type: none"> ○ AJL VISC 1.4% ○ AJL VISC 2% ○ AJL VISC 3% • AJLCELL (HPMC) <ul style="list-style-type: none"> ○ AJLCELL 2% 	IIb
Eye dye GMDN: 45180	<ul style="list-style-type: none"> • AJL BLUE OPHTHALMIC SOLUTION <ul style="list-style-type: none"> ○ TRIPAN BLUE AJL BLUE 0.06% ○ BRILLIANT BLUE AJL BBG 0.025% • TC BLUE OPHTHALMIC SOLUTIONS 	IIb
Scleral Implant GMDN: 37283	<ul style="list-style-type: none"> • ESNOPER <ul style="list-style-type: none"> ○ ESNOPER V-2000 ○ ESNOPER CLIP 	IIb
Orbital Sphere Implant GMDN: 46902	<ul style="list-style-type: none"> • OCULFIT ORBITAL IMPLANT <ul style="list-style-type: none"> ○ POI 	IIb
Non active Ophthalmologic devices MD0105	<ul style="list-style-type: none"> • AJL Perforated Conformer • AJL Symblepharon Ring • AJL Ocular Shield 	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

AJL OPHTHALMIC, S.A.	Ferdinand Zeppelin 1, Parque Tecnológico de Alava, 01510, Minaño
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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate