



Cert. 93/42/IP- Rev: 20/02/2003

CERTIFICADO CE DE SISTEMA COMPLETO DE GARANTIA DE CALIDAD de acuerdo con el Anexo II (Excepto punto 4) de la Directiva 93/42/CEE

EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE in accordance with Annex II (except Section 4) of Directive 93/42/EEC

PRÓRROGA/EXTENSION- Fecha inicial / Initial date: 2 de octubre de 2000

Certificado n°/Certificate no	Fecha de validez/Date of validity	ON n°/NB no
2000 10 0284 CT	* Desde/From 19-12-2005 Hasta/To 1-10-2010	0318

A favor de /In favour of:

<p>Fabricante/Manufacturer: Nombre/Name: AJL OPHTHALMIC, S.A Dirección/Address: Parque Tecnológico de Alava, Edificio E-3.- 01510- Miñano-Alava. Representante autorizado ante la UE/Authorized EU representative: Nombre/Name: AJL OPHTHALMIC, S.A. Dirección/Address: Parque Tecnológico de Alava, Edificio E-3.- 01510-Miñano-Alava.</p>
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Para el producto/For the product:

<p>Categoría/Category: Producto Sanitario Implantable No activo/ Non Active Implantable Device. Grupo genérico/Generic group: Implantes clínicos intraoculares / Intraocular Implants. Tipo/Type: Especificados en Anexos de este Certificado/Specified in Annexes to this Certificate.</p>
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Elaborado en/In the facilities:

<p>AJL OPHTHALMIC, S.A Parque Tecnológico de Alava, Edificio E-3. 01510- Miñano-Alava.</p>

Este certificado debe ir acompañado por certificado de examen de diseño: SI / NO

This certificate must be accompanied by design examination certificate YES/ NO

Este certificado es consecuencia de la auditoría del sistema de garantía de calidad de la producción y del examen de la documentación técnica contenida en el expediente nº 96 11 0037 y garantiza que los productos descritos cumplen los requisitos de la Directiva.

This certificate is issued on the production quality assurance system audit, and the examination of the technical documentation contained in dossier no. 96 11 0037, and guarantees that the described products fulfils the requirements of the Directive.

* Este certificado sustituye al emitido con fecha 30 de septiembre de 2005, al observar que el formato utilizado no correspondía al Certificado CE de Sistema Completo de Garantía de Calidad, y la fecha de inicio del período de validez debía constar el 30 de septiembre de 2005.

* *This certificate replaces that issued on date 30th September, 2005, due to the fact that the pattern is not suitable for the assessment by full quality assurance system and the date of validity should start on 30th september 2005.*

Madrid, 19 de Diciembre de 2005



agencia española de medicamentos y productos sanitarios

La Directora

ORGANISMO NOTIFICADO

0318

M^a del Val Díez Rodríguez



DET NORSKE VERITAS

FULL PRODUCT QUALITY MANAGEMENT CERTIFICATE - EC

Certificate No. 36146-2008-CE-NOR
This Certificate consists of 3 pages

This is to certify that the Quality Management System of

AJL OPHTHALMIC, S.A.

Miñano, Spain

for 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 H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 13 October 2008

This Certificate is valid until:

13 October 2013

For DET NORSKE VERITAS CERTIFICATION AS
Norway



Notified Body No.:
0434


Marianne Spæren

Certification Manager


Jenny Helen Nytn

Technical Reviewer

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300.000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.