

Certificate

Full Quality Assurance System Approval Annex II.3 of the Directive on Medical Devices

ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex II.3 of the Directive 93/42/EEC.



This certificate is issued on behalf of:

Manufacturer

Imperial Medical Technologies

30 Curtis Court; 300 Cartersville; Georgia
United States

EU-Representative

Imperial Medical Technologies Europe GmbH

Bergweg 8; D-59427 Unna; Germany

ECM certifies that the full quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex II.3 of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Audit Report Number
342-08-618

Registered under
Z/09/01839

Valid until
April 16th 2012

Aachen, May 25th 2009


Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-926.94.08

Annex I of Certificate Z/09/01839

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Zertifizierungsgesellschaft für
Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code
Ophthalmic and optical products	Intraocular lenses	/
	- Hydrophilic foldable acrylic intraocular lenses	
	- PMMA intraocular lenses	
Ophthalmic and optical products	Capsular tension rings	/
Ophthalmic and optical products	Keratacx, Intra-Stromal-Inlay	/

Special terms of validity:

None.

Certificate

Production Quality Assurance System Approval Annex V of the Directive on Medical Devices

ECM, Bismarckstr.106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex V of the Directive 93/42/EEC.



This certificate is issued on behalf of:

Manufacturer

Imperial Medical Technologies

30 Curtis Court; 300 Cartersville; Georgia
United States

EU-Representative

Imperial Medical Technologies Europe GmbH

Bergweg 8; D-59427 Unna; Germany

ECM certifies that the quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex V of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

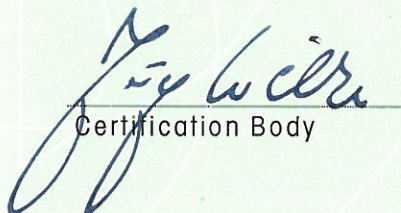
Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex V of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Report Number
342-08-618

Registered under
Z/09/01840

Valid until
April 16th 2012

Aachen, May 25th 2009


Certification Body



Akkreditiert durch
Zentralstelle der Länder
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bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-926.94.08

Annex I to Certificate Z/09/01840

Number of Pages: 1



Zertifizierungsgesellschaft für
Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Single use devices	Cartridges	/
Single use devices	Disposable Tips	/
Single use devices	Disposable Injectors	/
Ophthalmic and optical products	Viscoelastic gels	/

Special terms of validity:

None.

¹ UMDNS Code is optional

Annex I to Certificate Z/09/01840

Number of Pages: 1

Date of revision: February 5th, 2010



This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Ophthalmic and optical products	Viscoelastic gels	/

Special terms of validity:

None.

¹ UMDNS Code is optional

Certificate

Quality Assurance

ecm, Eifelstr. 1c, 52068 Aachen hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2007.

Through an audit performed on behalf of

Imperial Medical Technologies

at the manufacturing site

30 Curtis Court; 300 Cartersville; Georgia United States

it could be demonstrated that a quality assurance system

according **DIN EN ISO 13485:2007**
to "Medical devices – Quality management systems – Requirements for regulatory purposes"

for the **design, manufacture, sterilization and distribution of intraocular lenses and accessories**

has been established and implemented.

This certificate is only valid under the conditions stated in the hereafter mentioned audit report. Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report Number	Registered under	Valid until
342-08-618	Z/08/01613	2012-04-16

Aachen, 2008-08-01


Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-052.05.01-46

