

EC Certificate

DGM – 683

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This is to certify that the quality system of

Visionary Medical Supplies, Inc.
6441 Enterprise Lane
Madison, WI 53719
USA

has been approved in conformity with the requirements of

Annex II, section 3.2 - Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law.

The scope of the certification is:

Design, manufacture and final inspection of implantable intraocular lenses for replacement of the human crystalline lens, capsular tension rings, ophthalmic suture needles and ophthalmic solutions in class IIb and of ophthalmic solutions in class IIa

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of DS Certificering A/S. This EC certificate is issued pursuant to the DS Certificering A/S rules for the certification of medical devices and entitles the certificate holder to affix the CE mark.



Bent Buus
Authorized person

Valid from: 2011-01-28
Valid until: 2014-06-30
Initial date of issue: 2009-06-30
Reference: aur2a1004v200f331

DS Certificering A/S

Notified Body, Identification No. 0543
Kollegievej 6, DK-2920 Charlottenlund, Denmark

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The following product families in class IIb are covered by the certificate:

Implantable intraocular lenses
Hydrophilic foldable lenses
Capsular tension rings
Ophthalmic solutions
Ophthalmic suture needles

The following product families in class IIa are covered by the certificate:

Ophthalmic solutions

The authorized EC representative:

mdi Europa GmbH
Langenhagener Straße 71
30855 Langenhagen
Germany

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