EC Certificate

Certificate Number: DGM – 683

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 Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as ammended and transposed into Danish law, excluding Annex II, section 4.

The certificate covers the following activities:

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

This EC certificate is issued in accordance with Presafe Denmark A/S' terms and conditions cf. Council Directive 93/42/EEC concerning medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the Directive.

Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue:	2017-06-22
Expires:	2022-06-22
Initial date of issue:	2009-06-30
Reference:	aur2a1701v310f331

Presafe Denmark A/S
Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark

Presafe®
A DNV & NEMKO COMPANY

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

Certificate number:	DGM – 683
Certificate type:	EC Certificate

Date of issue:	2017-06-22
Expires:	2022-06-22
Initial date of issue:	2009-06-30
Reference:	aur2a1701v310f331

Presafe®
A DNV & NEMKO COMPANY

DGM