



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company



Vitreco

Vitreco B.V.

Seggelant-Noord 2
3237 MG Vierpolders
Netherlands

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Non-active ophthalmologic devices according to annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	527668 MR2
Certificate unique ID	170712954
Effective date	2018-07-01
Expiry date	2021-08-18
Frankfurt am Main	2018-04-10

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
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Vitrex B.V.

Seggelant-Noord 2
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Device family	Device	GMDN	Class
Silicone Oils	Sil-Vit	45125	IIb
Eye Dye	TreQ-Blue	45180	IIb
Perfluorocarbons	Deca-Vit & Octa-Vit	45283	IIa
Laser Probes	90° Directional (Illuminated)	61162	IIa
Light Fibers	Light Fibers	45193	IIa
Fluid Applicator	Dye Squeezer & PFC Squeezer	60793	Is
Disposable Backflush Instruments	Disposable Backflush Instruments	47130	IIa
Vitrectomy lenses	Vitrectomy lenses	58070	Is
Irrigation Aspiration Cannulas	Irrigation Aspiration Cannulas	46705	IIa
Disposable Forceps and Scissors	Disposable Forceps	62478	IIa
	Disposable Scissors	46728	IIa