

Certificate

Full Quality Assurance System Approval
Annex II excluding (4) 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 excluding (4) of the Directive 93/42/EEC.

This certificate is issued on behalf of:

Manufacturer

RUMEX INTERNATIONAL LTD

311 Shoreham Street, Sheffield, Yorkshire S24FA, United Kingdom

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 excluding (4) 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
571-15-318

Registered under
Z/16/03727E

Valid until
January 12th, 2021

Aachen, January 13th, 2016


Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-240.10.12

Annex I of Certificate Z/16/03727E

Page 1 of 1

Date of revision: February 9th, 2018



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
ophthalmic and optical products	Silicone oil - SmartSil 1000 - SmartSil 5000	Generic Term: 45125
ophthalmic and optical products	Lenses, Intraocular - AquaFree Yellow Aspheric Hydrophobic - AquaFree Yellow Preloaded - Hydro-Sense Aspheric - Hydro-Sense Aspheric Yellow - Hydro-4 Aspheric	UMDNS-Code: 12-324
ophthalmic and optical products	Aqueous/Vitreous Humor Replacement Media - Supreme Visoelastic Surgical Fluid	UMDNS-Code: 16-844

Special terms of validity:

None.

¹ Generic Term is optional