

# 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 undermentioned 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

**RUMEX INTERNATIONAL LTD**

**311 Shoreham Street, Sheffield, Yorkshire S24FA, United Kingdom**

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.

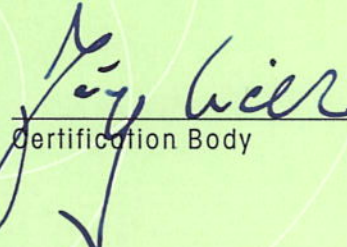
The approved quality assurance system is subject to periodic surveillance as defined by Annex V, section 4.

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	Registered under	Valid until
<b>571-19-524</b>	<b>Z/20/04649E</b>	<b>June 30<sup>th</sup>, 2021</b>

Valid as of: January 24<sup>th</sup>, 2020

  
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 to Certificate Z/20/04649E

Number of Pages: 1 of 1



This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code <sup>1</sup>
Ophthalmic and optical products	Shields, Mechanical, Eye -- SmartVisc -- SmartVisc PLUS	11-663
Ophthalmic and optical products	Ophthalmic Sponges -- PVA Spears -- PVA Points -- Cellulose Spears -- Cellulose Points -- Corneal Light Shield -- LASIK Shield -- LASIK Drain -- Instrument Wipe	/
Ophthalmic and optical products	Forceps, Ophthalmic	16-209
Ophthalmic and optical products	Scissors, Eye	13-485
Ophthalmic and optical products	Hooks	12-028
Ophthalmic and optical products	Cannulae, Eye	10-573
Ophthalmic and optical products	Specula, Eye	13-663
Ophthalmic and optical products	Needle Holders	12-726
Ophthalmic and optical products	Calipers, Ophthalmic	16-415

Special terms of validity:

In case of class I products or sterile procedure packs acc. to article 12 (3) of the Directive 93/42/EEC the intervention of ecm is limited to aspects of manufacture concerned with securing and maintaining sterile conditions respectively the conformity with the metrological requirements.

<sup>1</sup> UMDNS Code is optional