HTCert

Health Technology Certification

EC-CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

This is to certify that the quality management system of

Rumex International Ltd.

311 Shoreham Street, Sheffield, South Yorkshire,
S2 4FA, United Kingdom

for design and manufacture of

Ophthalmic devices

Further details are given overleaf

Certificate No:	**2379C04210501**
Issue Date:	**23/05/2021**
Original Approval:	**23/05/2021**
Valid until:	**26/05/2024**
References:	**WO01 2379 01**

HTCert is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification number **2803**

fulfills the requirements of Annex II excluding (4) of Council Directive 93/42/EEC.

The use of CE Marking followed by the HTCert Notified Body identification number 2803 for the devices listed on the certificate is hereby authorised. The certificate remains valid subject to satisfactory surveillance audits, periodic or unexpected. Any significant changes in design or manufacture may render this certificate invalid. For class III devices covered by this certificate an EC Design Examination Certificate according to Annex II, Section 4 is required. For class I sterile devices the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director

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Attachment to Certificate

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Products included:

Class IIb

- SmartSil 1000 & SmartSil 5000 Purified silicone oils
- SmartVisc and SmartVisc Plus Viscoelastic Solutions
- Supreme Viscoelastic surgical fluid

Class IIa

- Disposable Ophthalmic Knives
- Forceps, Ophthalmic
- Scissors, Eye
- Hooks
- Cannulae, Eye

Class Is

- Specula, Eye
- Needle Holders

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