	Rumex International Ltd **Declaration of Conformity** Supreme Viscoelastic surgical fluid	**Doc. No.:** DOC-05	**Date of Issue:** 21.03.2022
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European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed

General Product Name:	Supreme Viscoelastic surgical fluid
Technical File:	TCF-06
Legal Manufacturer and address:	Rumex International Lid. 311 Shoreham Street, Sheffield, South Yorkshire, S2 4FA, UK
European Representative and address:	RUMEX BALTICS SIA Robezu iela 46, Riga, LV-1004
Classification Class, Rule:	Class IIb according to the Rule 8
Notified Body:	G.F.I. Health Technology Certification Ltd Jacovides Tower 81-83 Grivas Digenis Avenue 1090 Nicosia Notified Body number: 2803
EC Certificate	Certificate number: 2379C04210501 Expiry Date: 26 May 2024
GMDN code:	35907 Vitreous/aqueous humor replacement medium, intraoperative
UMDNS code:	16844 Aqueous/Vitreous Humor Replacement Media
Conformity Assessment Procedure:	Annex applied: II excluding (4)

Authorized signature: _____

Name: Yulia Sterlikova

Position: Director

Appendix A

List of Applicable Standards

ISO 13485:2016/EN ISO 13485:2016/AC:2016	Medical devices -Quality Management Systems- particular requirements for regulatory purposes
ISO 10005:2005	Quality management systems - Guide lines for quality plans
EN ISO 17665-1:2006	Sterilization of health care products- Moist heat - Requirements for the development validation & routine control of sterilization process for medical device
EN 62366:2008	Medical devices-Application of usability engineering to medical device
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 15798:2010 / ISO 15798:2013 Amd 2017	Ophthalmic implants - Ophthalmic viscosurgical devices
EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part-1:Requirements for terminally sterilized medical devices
EN ISO 11737- 1:2006/AC:2009	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11607-1:2009 / ISO 11607-1:2006: AC 2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006 / ISO 11607-2:2006:AC 2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN 868-5:2009	Packaging materials and system for medical devices which are to be sterilized - Heat and self sealable pouches and reels of paper and plastic film construction - Requirements and test methods
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-17:2009	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of materials

EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
ISO 2248:1985	Packaging -- Complete, filled transport packages -- Vertical impact test by dropping
ISO 15223-1:2016	Graphical symbols for use in the labeling of medical devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
ISO 14644-1:2015	Clean rooms and assosiated controlled environments - classification of air cleanliness
ISO 14644-2:2015	Clean rooms and assosiated controlled environments - Specification for testing and monitoring to prove continued compliance with ISO 14644-1
ISO 14698 -1:2003	Clean rooms and associated controlled environment - Biocontamination control - General principles and methods
ISO 14698 -2:2003	Cleanrooms and associated controlled environments -- Biocontamination control -Part 2: Evaluation and interpretation of biocontamination data
MEDDEV 2.7/1, rev-4:2016	Clinical investigation, clinical evaluation - Guide for manufacturers and notified bodies
ICMED 13485:2016	Technical criteria for certification of medical devices