

### **Rumex International Ltd**

### **Declaration of Conformity**

Purified silicone oils SmartSil1000cSt & SmartSil 5000cSt

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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

<b>General Product Name:</b>	- SmartSil 1000cSt;
	- SmartSil 5000cSt.
Technical File:	TCF-03
Legal Manufacturer and	Rumex International Lid.
address:	311 Shoreham Street, Sheffield, South Yorkshire, S2 4FA, UK
<b>European Representative</b>	RUMEX BALTICS SIA
and address:	Robezu iela 46, Riga, LV-1004
<b>Classification Class, Rule:</b>	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:	45125 Vitreous humour replacement medium, postoperative
<b>UMDNS code:</b>	23965 Silicone Oil, Intraocular
<b>Conformity Assessment</b>	Annex applied: II excluding (4)
Procedure:	

Authorized signature

Name:

Yulia Sterlikova

Position: Director



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# Appendix A

## **List of Applicable Standards**

ISO 2248:1985	Packaging — Complete, filled transport packages — Vertical impact test by dropping
ISO 8655-2:2002/Cor 1:2008	Piston-operated volumetric apparatus — Part 2: Piston pipettes
ISO 8655-6:2002/Cor 1:2008	Piston-operated volumetric apparatus — Part 6: Gravimetric methods for the determination of measurement error
ISO 9001:2015	Quality management systems — Requirements
ISO 10012:2003	Measurement management systems — Requirements for measurement processes and measuring equipment
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-7:2008/Cor 1:2009	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
ISO 10993-9:2019	Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products
ISO 10993-10:2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
ISO 10993-13:2010	Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices
ISO 10993-16:2017	Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables
ISO 11135:2014/Amd 1:2018	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11138-7:2019	Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results
ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
ISO 11737-2:2019	Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14155:2011/Cor 1:2011	Clinical investigation of medical devices for human subjects — Good clinical practice — Technical Corrigendum 1



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ISO 14644-1:2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
ISO 14644-5:2004	Cleanrooms and associated controlled environments — Part 5: Operations
ISO 14971:2019	Medical devices — Application of risk management to medical devices
ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (Corrected version 2017-03)
ISO 20857:2010	Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices
MDD 93/42/EEC	Medical Device Directive
NF EN ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
NF EN ISO 11737-2:2020	Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
NF EN ISO 13485:2016	Medical Devices — Quality Management Systems — Requirements For Regulatory Purposes
NF EN ISO 14155:2012	Clinical investigation of medical devices for human subjects — Good clinical practice
NF EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
NF EN ISO 17665-1:2006	Sterilization of health Care Products — Moist Heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
NF EN 556-1:2002	Sterilization of medical devices — Requirements for medical devices to be designated STERILE — Part 1: Requirements for terminally sterilized medical devices
NF EN 1041+A1:2013	Information supplied by the manufacturer of medical devices