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:	Disposable Instruments
Technical File:	TCF-08
Legal Manufacturer and address:	Rumex International Ltd. 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:	- Forceps, Ophthalmic Class IIa according to the Rule 6; - Scissors, Eye Class IIa according to the Rule 6; - Hooks Class IIa according to the Rule 6; - Cannulae, Eye Class IIa according to the Rule 6; - Specula, Eye Class I s according to the Rule 1; - Needle Holders I s according to the Rule 1;
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
UMDNS code:	- Forceps, Ophthalmic Class 16209 Forceps, Ophthalmic; - Scissors, Eye Class 13485 Scissors, Surgical, Eye; - Hooks Class 12028 Hooks; - Cannulae, Eye 10573 Cannulae, eye; - Specula, Eye 13663 Specula, Ocular; - Needle Holders 12736 Suture Needle Holding;
Conformity Assessment Procedure:	Annex applied: II excluding (4)

Authorized signature: _____

Name: Sergey Vlasov

Position: QMR

Appendix A

List of Applicable Standards

ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 11137-1:2015	Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-2:2015	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose
EN ISO 7153-1:2016	Surgical instruments — Materials — Part 1: Metals
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 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993-12:2021	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
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
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
EN 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
EN 17141:2020	Cleanrooms and associated controlled environments - Biocontamination control
EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN 556-1:2001/AC:2011	Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN 62366-1-2015	Medical devices — Application of usability engineering to medical devices
MEDDEV. 2.7.1:2016.4	Clinical evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC