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:	Knives, Ophthalmic
Technical File:	TCF-07
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 IIa according to the Rule 6
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:	46741 Ophthalmic knife, single-use
UMDNS code:	27200 Blades, Surgical Scalpel
Conformity Assessment Procedure:	Annex applied: II excluding (4)

Authorized signature: _____

Name: Yulia Sterlikova

Position: Director

Appendix A. List of Applicable Standards

EN ISO 14971: 2012	Medical devices Application of risk management to medical devices
EN 62366:2015	Medical devices. Application of usability engineering to medical devices
EN ISO 10993-1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-7: 2018/AMD 1:2019	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals — Amendment 1: Applicability of allowable limits for neonates and infants
MEDDEV 2.7.1, rev.4	Clinical Evaluation: A guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC
EN ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ISO 14644-1: 2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
ISO 14698-2:2003/COR 1:2004	Cleanrooms and associated controlled environments — Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data — Technical Corrigendum 1
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2019	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11140-1:2014	Sterilization of health care products — Chemical indicators — Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
ISO 11135: 2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
EN 556-1: 2001	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
ISO 11138-2: 2017	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
ISO 7153-1:2016	Surgical instruments - Materials - Part 1: Metals
ISO 2859-1:1999/AMD 1:2011	Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection — Amendment 1
USP	United States Pharmacopeia
IP	Indian Pharmacopoeia