	Rumex International Ltd **Declaration of Conformity** AquaFree Yellow Aspheric Hydrophobic AquaFree Yellow Preloaded	**Doc. No.:** DOC-02	**Date of Issue:** 12.07.2022
		Rev. №: 8	**Page 1 of 3**

This EU declaration of conformity was issued under the sole responsibility of the below listed manufacturer in conmliance with European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices

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

General Product Name:	AquaFree Yellow Aspheric Hydrophobic; AquaFree Yellow Preloaded.
Technical File:	TCF-01
Legal Manufacturer and address:	Rumex International Lid. 311 Shoreham Street, Sheffield, South Yorkshire, S2 4FA, UK SRN: GB-MF-000023374
European Representative and address:	RUMEX BALTICS SIA Robezu iela 46, Riga, LV-1004 SRN: LV-AR-000008795
Classification Class, Rule:	Class IIb according to the Rule 8
Notified Body:	Kiwa Belgelendirme Hizmetleri A.Ş. Tepeören Mevkii Ankara Asfaltı Maret Arkası ITOSB 9. Cadde No: 15 Tuzla Istanbul Notified Body number: 1984
EC Certificate	Certificate number: 1984-MDD-21-818 Expiry Date: 27 May 2024
GMDN code:	35658 Posterior chamber IOL, Pseudophakic
UMDNS code:	12324 Lenses, Intraocular
Conformity Assessment Procedure:	Annex applied: II

Authorized signature: _____

Name: Sergey Vlasov

Position: Quality Management representative

Appendix A

List of Applicable Standards

EN ISO 13485:2016** EN ISO 13485:2016/A11:2021**	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 11979-2:2014	Ophthalmic implants – Intraocular lenses – Part 2: Optical properties and test methods
ISO 11979-3:2012	Ophthalmic implants – Intraocular lenses – Part 3: Mechanical properties and test methods
ISO 11979-4:2008 + Amd1:2012	Ophthalmic implants – Intraocular lenses – Part 4: Labelling and information
ISO 11979-5:2020	Ophthalmic implants – Intraocular lenses – Part 5: Biocompatibility
ISO 11979-6:2014	Ophthalmic implants – Intraocular lenses – Part 6: Shelf-life and transport stability
EN ISO 11135-1:2014** EN ISO 11135:2014/A1:2019**	Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 14971:2012* ISO 14971:2019 ISO/TR 24971:2020	Application of risk management to medical devices Medical devices – Guidance on the application of ISO 14971
ANSI Z80.7:2013 (R2018)	Ophthalmic Optics – Intraocular lenses
EN ISO 15223-1:2021**	Medical Devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
EN 1041:2008*	Terminology, Symbols and information Provided with Medical Devices – Information Supplied by the Manufacturer with Medical Devices
EN ISO 11979-8:2009* ISO 11979-8:2017	Ophthalmic Implants – Intraocular Lenses – Part 8: Fundamental Requirements
EN ISO 10993-1:2009* ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management 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 ISO 11607- 1:2009*	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 14644-3:2019	Clean rooms and associated controlled environments - Part 3: Test methods
ISO 14644-4:2001	Clean rooms and associated controlled environments - Part 4: Design, construction and start-up
EN ISO 14644-5:2004	Clean rooms and associated controlled environments - Part 5: Operations
ASTM F1886 /F1886M-13	Standard Test Method Determining integrity of Seals for Medical Packaging by Yisual Inspection
ASTM F1929-15	Standard Test method for Detecting Seal Leaks in porous Medica\ Packaging by Dye Penetration
ISO 2248:1985	Packaging- Complete Filled Transport Packages - Yertical Impact Test by Dropping
IEC 62366-1:2015+Amd 1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
ISO 20417:2021	Medical devices - information to be supplied by the manufacturer

*Harmonized standard versions

List of Regulations Applied on the Medical Device

Regulation Reference Title	Year	Regulation Title
MDD 93/42/EEC As amended 2007/47/EC	1993 2007	Council Directive concerning Medical Devices
MEDDEV 2.4/1 rev.9	2010	Medical Devices: Guidance document – Classification of Medical Devices
MEDDEV 2.7.1/rev.4	2016	Clinical Evaluation: A Guide for Manufacturer and NB under Directives 93/42/EEC and 90/385/EEC
MEDDEV 2.7/3 rev.3	2015	Clinical Investigations: Serious Adverse Event Reporting under Directives 90/385/EEC and 93/42/EEC
MEDDEV 2.10-2 rev.1	2001	Designation and Monitoring of NB within the Framework of EC Directives on Medical Devices
MEDDEV 2.12-1 rev.8	2013	Guidance on a Medical Device Vigilance System
MEDDEV 2.12/2 rev.2	2012	Market Surveillance – Post Market Clinical Follow-up Studies
NBOG-BPG-2014-3	2014	Guidance for manufacturers and NB on reporting of Design Changes and Changes of the Quality System
GHTF SG3	2004	QMS – Process Validation Guidance