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:	– 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
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:	Kiwa Belgelendirme Hizmetleri A.Ş. Tepeören Mevkii Ankara Asfaltı Maret Arkası ITOSB 9. Cadde No: 15 Tuzla Istanbul Notified Body number: 1984
GMDN code:	35658 Posterior chamber IOL, Pseudophakic
UMDNS code:	12324 Lenses, Intraocular
Conformity Assessment Procedure:	Annex applied: II

Authorized signature: _____

Name: Yulia Sterlikova

Position: Director

Appendix A

List of Applicable Standards

EN ISO 13485:2016*	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 + Amd 1:2012	Ophthalmic implants - Intraocular lenses - Part 4: Labeling and information
ISO 11979-5:2006	Ophthalmic implants - Intraocular lenses - Part 5: Biocompatibility
ISO 11979-6:2014	Ophthalmic implants - Intraocular lenses - Part 6: Shelf-life and transport stability
ISO 11979-7:2018	Ophthalmic Implants – Intraocular Lenses – Part 7: Clinical Investigations
ISO 11979-8:2017 EN ISO 11979-8:2009*	Ophthalmic Implants – Intraocular Lenses – Part 8: Fundamental Requirements
ISO 11135-1:2014 EN ISO 11135-1:2007*	Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
ISO 14971:2019 EN ISO 14971:2019*	Medical devices – Application of Risk Management to Medical Devices
ISO/TR 24971:2020	Medical devices – Guidance on the application of ISO 14971
ANSI Z80.7:2013	Ophthalmic Optics - Intraocular Lenses
EN 15223-1:2016*	Medical Devices - Symbols to be used with the medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041:2008*	Terminology, Symbols and information Provided with Medical Devices - Information Supplied by the Manufacturer with Medical Devices
ISO 11607-1:2019 EN ISO 11607-1:2009*	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019 EN ISO 11607-2:2006*	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 14155:2011* EN ISO 14155-1:2011/AC:2011*	Clinical Investigation of Medical Device in Human Subjects – Part 1: General Requirements
ISO 10993-1:2018 EN ISO 10993-1:2009* EN ISO 10993-1:2009/AC:2010*	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 14644-3:2015*	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 14644-4:2001*	Cleanrooms and associated controlled environments - Part 4: Design, construction and start-up
EN ISO 14644-5:2004*	Cleanrooms and associated controlled environments - Part 5: Operations
IEC 62366-1:2015 IEC 62366-1/Amd 1:2020	Medical Devices – Part 1: Application of usability engineering to medical device
ASTM F1886/F1886M-16	Standard test method for determining integrity of seals for flexible packaging by visual inspection
ASTM F1929-15	Standard test method for detecting seal leaks in porous medical packaging by dye penetration
ASTM F2096-04	Standard test method for detecting gross leaks in medical packaging by internal pressurization (bubble test)

*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