Declaration of Conformity

We, **Rumex International LTD**
311 Shoreham Street, Sheffield,
South Yorkshire, S2 4FA, UK

declare on our own responsibility that the medical devices:

SmartSil 1000	(Class II b, Rule 8)
SmartSil 5000	(Class II b, Rule 8)
AquaFree Aspheric Yellow	(Class II b, Rule 8)
AquaFree Yellow Preloaded	(Class II b, Rule 8)
Hydro-Sense Aspheric	(Class II b, Rule 8)
Hydro-Sense Aspheric Yellow	(Class II b, Rule 8)
Hydro-4 Aspheric	(Class II b, Rule 8)
Supreme Viscoelastic Surgical Fluid	(Class II a, Rule 6)

conform with the appropriate requirements of the **MDD 93/42/EEC (2007/47/EC) Annex II excl. (4)**
CE certificate # Z/16/03727E valid until 12.01.2021

and

SmartVisc	(Class II a, Rule 6)
SmartVisc PLUS	(Class II a, Rule 6)
Ophtalmic Sponges	(Class I sterile, Rule 1&4)
Forceps, Ophthalmic	(Class II a, Rule 6)
Scissors, Eye	(Class II a, Rule 6)
Hooks	(Class II a, Rule 6)
Cannulae, Eye	(Class II a, Rule 6)
Specula, Eye	(Class I s, Rule 6)
Needle Holders	(Class I s, Rule 6)
Calipers, Ophthalmic	(Class I m, Rule 6)

conform with the appropriate requirements of the **MDD 93/42/EEC (2007/47/EC) Annex V**
CE certificate # Z/15/03647E valid until 25.08.2020

and

Rumex International LTD was certified for the compliance to **ISO 13485:2016** by ***ECM-ZERTIFIZIERUNGSGESELLSCHAFT FÜR MEDIZINPRODUKTE IN EUROPA MBH***
Bismarckstraße 106, AACHEN, 52066, Germany

CE-Mark **0481**

Rumex International Ltd.

Yulia Sterlikova
Director