Rumex International LTD
311 Shoreham Street, Sheffield,
South Yorkshire, S24FA, UK

Date: 26 May 2024

Confirmation Letter
Reference: GB_023374_2024_01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, HTCert, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2803 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Rumex International ltd.
311 Shoreham Street, Sheffield, South Yorkshire, S24FA, UK
SRN: GB-MF-000023374

Application ID: GB023374_2023_10_02
Application Date: 26/01/2024
Contract for MDR certification signed on 28/01/2024

The devices covered by the formal application and the written agreement mentioned above are identified below. HTCert is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)

- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Filippos Kottis
Certification Director

Devices covered by this letter

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
AquaFree Yellow Aspheric Hydrophobic Intraocular Lenses	IIb	n/a	1984-MDD-21-818 NB 1984
AquaFree Yellow Preloaded Hydrophobic Intraocular Lenses	IIb	n/a	1984-MDD-21-818 NB 1984
SmartSil 1000 Purified Silicone Oil	IIb	n/a	2379C04210501 NB 2803
SmartSil 5000 Purified Silicone Oil	IIb	n/a	2379C04210501 NB 2803
SmartVisc Viscoelastic Solution	IIb	n/a	2379C04210501 NB 2803
SmartVisc PLUS Viscoelastic Solution	IIb	n/a	2379C04210501 NB 2803
Supreme Viscoelastic Surgical Fluid	IIb	n/a	2379C04210501 NB 2803
Disposable Ophthalmic Knives	IIa	n/a	2379C04210501 NB 2803
Forceps, Ophthalmic	IIa	n/a	2379C04210501 NB 2803
Scissors, Eye	IIa	n/a	2379C04210501 NB 2803
Hooks	IIa	n/a	2379C04210501 NB 2803
Cannulae, Eye	IIa	n/a	2379C04210501 NB 2803
Specula, Eye	Is	n/a	2379C04210501 NB 2803
Needle Holders	Is	n/a	2379C04210501 NB 2803

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/26	GB_023374_2024_01	Initial issue