ALCHIMIA
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Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	AL.CHI.MI.A. S.r.l.
Manufacturer address and contact details	Viale Austria, 14 35020 – Ponte San Nicolò (PD) Italy regolatorio@alchimiasrl.com
Single Registration Number (SRN) (if available)	IT-MF-000028901

Authorised Representative name (if applicable)	Not applicable
Authorised Representative address and contact details	Not applicable
Single Registration Number (SRN) (if available)	Not applicable

Notified body name (if applicable)	☒ See attached schedule
Notified body number (if applicable)	☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☒ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☒ See attached schedule
End date of extended validity/transition period	☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☒ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

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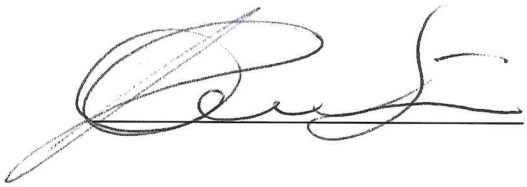
Signed for and on behalf of the manufacturer:

AL.CHI.MI.A. S.r.l.

Viale Austria, 14 – 35020 Ponte San Nicolò (PD) – Italy, 29.04.2024

Alessandro Vinti, CEO Managing Director

regolatorio@alchimiasrl.com



Stamp:

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] Family name	**Device name, catalogue number and risk class according to MDD**	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Products and accessories for Eye Banking: devices for rinsing, storage and transport of tissues for eye surgery	**Corneal Chamber** (CTC 001-01) *Class IIa*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Kiwa Cermet Italia S.P.A. 0476	December 31th, 2028	N/A
	PSS-L (GRS 003-00) *Class IIa*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Kiwa Cermet Italia S.P.A. 0476	December 31th, 2028	N/A
	Corneal Float (CFD 001) *Class Is*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Istituto Superiore di Sanità 0373	December 31th, 2028	N/A
	Kerasave (KER 002-00) *Class IIa*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Kiwa Cermet Italia S.P.A. 0476	December 31th, 2028	N/A
Reversible tissue dyes used to visualize tissues to be extirpated	**RS-BLUE** (RSB 001-00, RSB 002-00)	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Eurofins Product Testing Italy 0477	December 31th, 2028	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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Identification of the device(s)[3] Family name	**Device name, catalogue number and risk class according to MDD**	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
during ophthalmic surgical procedures	*Class IIa*						
	viewILM (RMB 003-00) *Class IIa*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Eurofins Product Testing Italy 0477	December 31th, 2028	N/A
	TWIN (RMB 004-00) *Class IIa*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Eurofins Product Testing Italy 0477	December 31th, 2028	N/A
Liquid and gaseous endotamponades for vitreoretinal surgery and related accessories	**RS-OIL** (RSO 002-00, RSO 003-00, RSO 004-00, RSO 005-00, RSO 008-00, RSO 009-00, RSO 012-00) **and RS-OIL ECS** (RSO 006-00, RSO 007-00, RSO 010-00, RSO 011-	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Eurofins Product Testing Italy 0477	December 31th, 2027	N/A

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	00, RSO 013-00) *Class IIb, implantable*						
	ECT (ECT 002-00, ECT 003-00, ECT 004-00) *Class Is*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Eurofins Product Testing Italy 0477	December 31th, 2028	N/A
	GOT (GOT 007-00, GOT 007-01, GOT 008-00, GOT 008-01, GOT 009-00, GOT 009-01) *Class IIb, implantable*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Eurofins Product Testing Italy 0477	December 31th, 2027	N/A
	GIS (GIS 001-00, GIS 003-00) *Class IIa*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Eurofins Product Testing Italy 0477	December 31th, 2028	N/A

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Perfluorocarbons for vitreoretinal surgery and accessories	**HPF 8** (HPF 001-00, HPF 002-00, HPF 019-00, HPF-20-00) *Class IIa*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Eurofins Product Testing Italy 0477	December 31th, 2028	N/A
	HPF 10 (HPF 003-00, HPF 004-00, HPF 021-00, HPF-22-00) *Class IIa*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Eurofins Product Testing Italy 0477	December 31th, 2028	N/A
Corneal protective devices during diagnostic tests (in diagnostics) or during surgical procedures	**eyeDRO** (EDO 001, EDO 002) *Class IIa*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Eurofins Product Testing Italy 0477	December 31th, 2028	N/A
	OCIGEL (OCI 001, OCI 002) *Class Is*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Eurofins Product Testing Italy 0477	December 31th, 2028	N/A
Products for the storage and transport of human tissues	**CRYO.ON** (CRN 001-00, CRN 002-00)	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Kiwa Cermet Italia S.P.A. 0476	December 31th, 2028	N/A

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intended for transplantation	*Class IIa*						
	GLYO.ON (GLY 001, GLY 002) *Class IIa*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Kiwa Cermet Italia S.P.A. 0476	December 31th, 2028	N/A
	BASE (BAS 007-00) *Class IIa*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Kiwa Cermet Italia S.P.A. 0476	December 31th, 2028	N/A
	BASE 128 (BAS 005-00, BAS 006-00) *Class IIa*	EPT 0477.MDD.21/4446	May 26th, 2024	Eurofins Product Testing Italy 0477	Kiwa Cermet Italia S.P.A. 0476	December 31th, 2028	N/A
Medical device for corneal storage, sterile	**TISSUE-C** *Class III*	QCT-0125-19	May 26th, 2024	Istituto Superiore di Sanità 0373	Istituto Superiore di Sanità 0373	December 31th, 2027	N/A
Medical device for corneal deswelling and transport, sterile	**CARRY-C** *Class III*	QCT-0125-19	May 26th, 2024	Istituto Superiore di Sanità 0373	Istituto Superiore di Sanità 0373	December 31th, 2027	N/A

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