F.L. MEDICAL s.r.l. Unipersonale
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e-mail: info@flmedical.com - web site: www.flmedical.com
C.F. e P.IVA 01134840287 - Cap Soc. 90.000 € i.v.
Reg. Imp. di Padova n. 21695 - R.E.A. di Padova n. 187254

DECLARATION OF CONFORMITY

MANUFACTURER	**FL MEDICAL SRL**
Headquarters	Torreglia (PD) - VIA ENRICO MATTEI, 20
CODES	See Annex – List of codes
DESCRIPTION	**Sterile test tubes for biological liquids collection** **Sterile containers for biological liquids collection**
CLASSIFICATION	Other type of IVD
REFERENCE QUALITY ASSESSMENT	Annex III of the Community Directive 98/79/EC on In vitro Diagnostic Medical Devices
DECLARES ON ITS RESPONSIBILITY THAT THE DEVICES MENTIONED ABOVE MEET THE ESSENTIAL REQUIREMENTS OF THE ANNEX I OF DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES. THE WHOLE PRODUCTION PROCESS FOLLOWS THE STANDARDS REQUIRED BY THE DIRECTIVE 98/79/EC. THE TECHNICAL DOCUMENTATION IS LOCATED IN OUR FACILITIES.	
PLACE AND DATE OF CURRENT EMISSION	Torreglia (PD) - VIA ENRICO MATTEI, 20 Date: 26/07/2022
DOCUMENTATION CONSERVATION PLACE	Torreglia (PD) - VIA ENRICO MATTEI, 20
SIGNATURE	**RAQ** Alessandro Fiore 

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ANNEX – LIST OF CODES

STERILE TEST TUBES FOR BIOLOGICAL LIQUIDS COLLECTION

Code	*Description*
25192GIM	URINE TEST TUBE 12 ml CONICAL IN POLYSTYRENE WITH RED CAP AND LABEL INDIVIDUALLY WRAPPED ST. IN SINGLE BOX "GIMA"
21151	PROMED ® TEST TUBE 12x86 mm 5 ml CYLINDRICAL IN POLYPROPYLENE WITH RED CAP AND LABEL STERILE IN BULK
21150	PROMED ® TEST TUBE 16x100 mm 10 ml CYLINDRICAL IN POLYPROPYLENE WITH RED CAP AND LABEL STERILE IN BULK
21153	PROMED ® TEST TUBE 12x86 mm 5 ml CYLINDRICAL IN POLYSTYRENE WITH RED CAP AND LABEL STERILE IN BULK
21152	PROMED ® TEST TUBE 16x100 mm 10 ml CYLINDRICAL IN POLYSTYRENE WITH RED CAP AND LABEL STERILE IN BULK
21409	PROMED ® TEST TUBE 17x120 mm 15 ml CONICAL IN POLYPROPYLENE RED SCREW CAP GRADUATED STERILE
21402	PROMED ® TEST TUBE 30x115 mm 50 ml CONICAL IN POLYPROPYLENE RED SCREW CAP GRADUATED STERILE
21404	PROMED ® TEST TUBE 30x115 mm 50 ml CONICAL IN POLYPROPYLENE RED SCREW CAP GRADUATED WITH SELF-STANDING BASE STERILE

STERILE CONTAINERS FOR BIOLOGICAL LIQUIDS COLLECTION

Code	*Description*
25178GIM	SUCTION URINE CONTAINER 120 ml IN POLYPROPYLENE WITH YELLOW SCREW CAP, WITH FROSTED LABEL, INDIVIDUALLY WRAPPED, STERILE IN SINGLE BOX "GIMA"
25177GIM	URINE CONTAINER 120 ml IN POLYPROPYLENE WITH SCREW CAP AND LABEL INDIVIDUALLY WRAPPED ST. IN SINGLE BOX "GIMA"
25193GIM	FAECES CONTAINER 60 ml IN POLYPROPYLENE WITH SCREW CAP AND LABEL INDIVIDUALLY WRAPPED IN SINGLE BOX "GIMA"
25035GIM	URINE CONTAINER 120 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL, INDIVIDUALLY WRAPPED, STERILE
25135GIM	FAECES CONTAINER 30 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL, INDIVIDUALLY WRAPPED, STERILE
25165GIM	FAECES CONTAINER 60 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL, INDIVIDUALLY WRAPPED, STERILE
25185GIM	URINE CONTAINER 60 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL, INDIVIDUALLY WRAPPED, STERILE
25198	URINTRANSFER ® VACUUM TUBE PET 16x100 mm WITHOUT ADDITIVE FOR 10 ml OF URINE, YELLOW CAP, INDIVIDUALLY WRAPPED, STERILE, IN SINGLE BOX

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Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- 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	F.L. Medical s.r.l.
Manufacturer address and contact details	Via Enrico Mattei, 20 – 35038 Torreglia (Padova), Italy
Single Registration Number (SRN) (if available)	IT-MF-000013918

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	☐ See attached schedule ☒ Not applicable
Notified body number (if applicable)	☐ See attached schedule ☒ Not applicable
Directive Certificate number(s) to which this confirmation is made (if applicable)	☐ See attached schedule ☒ Not applicable
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)	☐ See attached schedule ☒ Not applicable

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End date of extended validity/transition period	☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the **device(s)** listed in the attached schedule the conditions for the legal extension of transitional periods as required in Article 110.3b of the IVDR are met *and/or*
- for the **Directive Certificate(s)** listed in the attached schedule the conditions for the legal extension of validity as required in Article 110.2 of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Devices which were self-declared under the IVDD and require notified body involvement under the IVDR**

In case of devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a notified body:

Choose applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body for the device(s) listed in the attached schedule or its/their substitutes no later than:

☐ 26 May 2025 for class D devices

☐ 26 May 2026 for class C devices

☒ 27 May 2027 for class B and class A (sterile) devices

☒ Signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the device(s) listed in the attached schedule or its/their substitutes no later than:

☐ 26 September 2025 for class D devices

☐ 26 September 2026 for class C devices

☒ 27 September 2027 for class B and class A (sterile) devices

☐ We do not intend to lodge an application for conformity for the device as indicated on the attached schedule.

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

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- Directive Certificate(s) covering the device(s) listed in the attached schedule was/were issued after 25 May 2017, was/were valid on 26 May 2022 and has/have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Original expiry date *before 9 July 2024*:

  ☐ 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 IVDR for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of its/their substitute(s), or

  ☐ Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 54(1) IVDR (may be provided upon request), or

  ☐ Competent Authority has required us as the manufacturer, in accordance with Article 92(1) IVDR, 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 54(1) or a requirement per Article 92(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 IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 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 IVDR before 26 September 2025.

  ☐ We do not intend to lodge an application for conformity assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.

  ☐ Original expiry date *after 9 July 2024*:

  Choose one applicable statement:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 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 IVDR before 26 September 2025.

  ☐ We do not intend to lodge an application for conformity assessment by 26 May 2025 for the devices as indicated on the attached schedule, therefore the transition period will end on 26 May 2025.

  ☐ assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.

➢ **Quality Management System (QMS)**

  Choose one applicable statement:

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- ☐ QMS in accordance with Article 10(8) IVDR will be put in place by no later than 26 May 2025.
- X QMS in accordance with Article 10(8) IVDR is in place.
- ☐ Notified body has issued the attached certificate for the IVDR-compliant QMS.

➢ **Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)**

- The device(s) continue(s) to comply with the IVDD.
- 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.

Signed for and on behalf of the manufacturer:

Full Company Name: F.L. Medical s.r.l.

Location & Date: Torreglia, 11.04.2025

Signature, Print Name, Title:

Alessandro Fiore

Quality Manager



Contact Details (at least email): info@flmedical.com

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Schedule of Devices

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

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)	**Directive Certificate number to which this declaration is issued** (if applicable)	**Original expiry date as indicated on the Directive Certificate 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 IVDR application was lodged/contract signed** (if applicable)
25185	31 December 2029	N/A	N/A	N/A	N/A	N/A
25035	31 December 2029	N/A	N/A	N/A	N/A	N/A
25135	31 December 2029	N/A	N/A	N/A	N/A	N/A
25165	31 December 2029	N/A	N/A	N/A	N/A	N/A
25178GIM	31 December 2029	N/A	N/A	N/A	N/A	N/A
25198	31 December 2029	N/A	N/A	N/A	N/A	N/A
25177	31 December 2029	N/A	N/A	N/A	N/A	N/A
25192	31 December 2029	N/A	N/A	N/A	N/A	N/A
25193	31 December 2029	N/A	N/A	N/A	N/A	N/A
21151	31 December 2029	N/A	N/A	N/A	N/A	N/A
21150	31 December 2029	N/A	N/A	N/A	N/A	N/A
21153	31 December 2029	N/A	N/A	N/A	N/A	N/A
21152	31 December 2029	N/A	N/A	N/A	N/A	N/A
21409	31 December 2029	N/A	N/A	N/A	N/A	N/A

[1] for devices with IVDD 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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21402	31 December 2029	N/A	N/A	N/A	N/A	N/A
21404	31 December 2029	N/A	N/A	N/A	N/A	N/A