F.L. MEDICAL s.r.l. Unipersonale
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C.F. e P.IVA 01134840287 - Cap Soc. 90.000 € i.v.
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DICHIARAZIONE DI CONFORMITA'

FABBRICANTE	**FL MEDICAL S.R.L. UNIPERSONALE**
SEDE LEGALE	Torreglia (PD) - VIA ENRICO MATTEI, 20
CODICI	ALLEGATO – Lista codici
DESCRIZIONE	**Provette sterili per raccolta liquidi biologici** **Contenitori sterili per raccolta liquidi biologici**
CLASSIFICAZIONE	Altro tipo di IVD
RIFERIMENTO VALUTAZIONE QUALITA'	Allegato III, Direttiva 98/79/CE
SI DICHIARA SOTTO LA PROPRIA RESPONSABILITA' CHE I DISPOSITIVI SOPRA MENZIONATI SONO STATI PRODOTTI IN CONFORMITA' ALL'ALLEGATO I DELLA DIRETTIVA 98/79/CE E PERTANTO SODDISFANO I REQUISITI DEI REGOLAMENTI IN VIGORE SUI DISPOSITIVI MEDICO-DIAGNOSTICI IN VITRO. **TUTTA LA DOCUMENTAZIONE A SUPPORTO E' CUSTODITA PRESSO GLI ARCHIVI DEL SISTEMA QUALITA' DEL FABBRICANTE SOTTO LA RESPONSABILTA' DEL RAQ.** **LA PRESENTE DICHIARAZIONE DI CONFORMITA' E' RILASCIATA SOTTO LA RESPONSABILITA' ESCLUSIVA DEL FABBRICANTE.**	
LUOGO E DATA EMISSIONE CORRENTE	Torreglia (PD) - VIA ENRICO MATTEI, 20 Data: 26/07/2022
LUOGO DI CONSERVAZIONE DELLA DOCUMENTAZIONE	Torreglia (PD) - VIA ENRICO MATTEI, 20
FIRMA	**RAQ** Alessandro Fiore 

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ALLEGATO – LISTA CODICI

PROVETTE STERILI PER RACCOLTA LIQUIDI BIOLOGICI

Codice	*Descrizione*
25192GIM	PR. 12 ml CONICA PER URINA IN POLISTIROLO CON TAPPO ROSSO + ET. CONF. SING. ST. IN ASTUCCIO "GIMA" (cod. 25990)
21151	PROMED ® PR. 12x86 mm 5 ml CILINDRICA IN POLIPROPILENE CON TAPPO ROSSO + ET. STERILE SFUSA
21150	PROMED ® PR. 16x100 mm 10 ml CILINDRICA IN POLIPROPILENE CON TAPPO ROSSO + ET. STERILE SFUSA
21153	PROMED ® PR. 12x86 mm 5 ml CILINDRICA IN POLISTIROLO CON TAPPO ROSSO + ET. STERILE SFUSA
21152	PROMED ® PR. 16x100 mm 10 ml CILINDRICA IN POLISTIROLO CON TAPPO ROSSO + ET. STERILE SFUSA
21409	PROMED ® PR. 17x120 mm 15 ml CONICA IN POLIPROPILENE TAPPO ROSSO A VITE GRADUATA STERILE
21402	PROMED ® PR. 30x115 mm 50 ml CONICA IN POLIPROPILENE TAPPO ROSSO A VITE GRADUATA STERILE
21404	PROMED ® PR. 30x115 mm 50 ml CONICA IN POLIPROPILENE TAPPO ROSSO A VITE GRADUATA CON BASE D'APPOGGIO STERILE

CONTENITORI STERILI PER RACCOLTA LIQUIDI BIOLOGICI

Codice	*Descrizione*
25178GIM	CONTENITORE 120 ml PER URINA, CON ASPIRAZIONE PR. SOTTOVUOTO, IN POLIPROPILENE TAPPO A VITE GIALLO, CONF. SING., STERILE, IN ASTUCCIO "GIMA" (cod. 25969)
25177GIM	CONTENITORE 120 ml PER URINA IN POLIP. TAPPO A VITE + ET. CONF. SING. ST. IN ASTUCCIO "GIMA" (cod. 25987)
25193GIM	CONTENITORE 60 ml PER FECI IN POLIP. TAPPO A VITE + ET. CONF. SING. ST. IN ASTUCCIO "GIMA" (cod. 25997)
25035GIM	CONTENITORE 120 ml PER URINA IN POLIPROPILENE TAPPO A VITE ROSSO, CON SUPERFICIE DI SCRITTURA, CONF. SING., STERILE
25135GIM	CONTENITORE 30 ml PER FECI IN POLIPROPILENE TAPPO A VITE ROSSO, CON SUPERFICIE DI SCRITTURA, CONF. SING., STERILE
25165GIM	CONTENITORE 60 ml PER FECI IN POLIPROPILENE TAPPO A VITE ROSSO, CON SUPERFICIE DI SCRITTURA, CONF. SING., STERILE
25185GIM	CONTENITORE 60 ml PER URINA IN POLIPROPILENE TAPPO A VITE ROSSO, CON SUPERFICIE DI SCRITTURA, CONF. SING., STERILE
25198	URINTRANSFER ® PR. 16x100 mm SOTTOVUOTO IN PET PER URINA SENZA ADDITIVO PER 10 ml DI URINA, TAPPO GIALLO, CONF. SING., STERILE, IN ASTUCCIO

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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