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

# EC DECLARATION OF CONFORMITY

| | |
|---|---|
| **MANUFACTURER'S NAME** | F.L. MEDICAL s.r.l. Unipersonale |
| **MANUFACTURER'S REGISTERED PLACE OF BUSINESS AND ADDRESS** | Via Enrico Mattei, 20 – 35038 Torreglia (PD) - Italy |
| **MANUFACTURER'S SINGLE REGISTRATION NUMBER (SRN)** | IT-MF-000013918 |
| **DEVICE NAME / TRADE NAME** | *Containers for biological liquids collection* |
| **DEVICE CODES** | **ref.: Annex I to the present Declaration of Conformity** |
| **RISK CLASS AND CLASSIFICATION RULE** | **Other type of IVD**<br>IVD not included in Annex II of Directive 98/79/EC, nor self-testing IVD |
| **INTENDED USE** | *Containers for biological liquids collection, for diagnostic test* |
| **COMMON SPECIFICATIONS** | *not applicable* |
| **BASIC UDI-DI** | *not applicable* |
| **NAME, ADDRESS AND IDENTIFICATION NUMBER OF THE NOTIFIED BODY** | *not applicable* |
| **CERTIFICATE NUMBER** | *not applicable* |
| **CONFORMITY ASSESSMENT PROCEDURE** | Preparation of the technical documentation (ref. Annex III of Directive 98/79/EC) and issue of the EC Declaration of Conformity. |
| **ADDITIONAL INFORMATION** | *not applicable* |
| **WE DECLARE UNDER OUR OWN RESPONSIBILITY THAT THE DEVICES ABOVE MENTIONED HAVE BEEN PRODUCED IN COMPLIANCE WITH PRODUCT SPECIFICATIONS, OPERATING INSTRUCTIONS AND LABELLING REQUIREMENTS AND THEREFORE MEET THE PROVISIONS OF THE LAWS IN FORCE ON IN VITRO DIAGNOSTIC MEDICAL DEVICES APPLIED FOR THE CONFORMITY ASSESSMENT PROCEDURE.<br>ALL THE SUPPORTING DOCUMENTATION IS RETAINED AT THE ARCHIVES OF MANUFACTURER'S QUALITY MANAGEMENT SYSTEM, UNDER THE RESPONSIBILITY OF RAQ.<br>THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER.** | |
| **PLACE OF DOCUMENTATION STORAGE** | Via Enrico Mattei, 20 – 35038 Torreglia (PD) - Italy |
| **PLACE AND DATE OF ISSUE OF THE PRESENT DECLARATION** | Via Enrico Mattei, 20 – 35038 Torreglia (PD) - Italy<br><br>Date: 10/03/2025 |
| **NAME, JOB TITLE AND SIGNATURE** | Alessandro Fiore<br>Quality Assurance Manager (RAQ)<br><br>Signature:  |

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## ANNEX I – LIST OF CODES

| DEVICE CODE / CATALOGUE NUMBER | DEVICE NAME |
|---|---|
| 25035 | Urintainer ® Urine container 120 ml in PP with red screw cap, with frosted label, individually wrapped, sterile |
| 25175 | Urintainer ® Urine container 30 ml in PP with red screw cap, with frosted label, individually wrapped, sterile |