F.L. MEDICAL s.r.l. Unipersonale
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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

EU 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	**Class A non-sterile** Rule 5, according to Annex VIII of the Regulation 2017/746.
INTENDED USE	Collection of biological liquids samples (urine and feces) for diagnostic testing
COMMON SPECIFICATIONS	*not applicable*
BASIC UDI-DI	8052109520004UD
NAME, ADDRESS AND IDENTIFICATION NUMBER OF THE NOTIFIED BODY	*not applicable*
CERTIFICATE NUMBER	*not applicable*
CONFORMITY ASSESSMENT PROCEDURE	Preparation of the technical documentation (ref. Annexes II and III of Regulation 2017/746) and issue of the EU 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.
ALL THE SUPPORTING DOCUMENTATION IS RETAINED AT THE ARCHIVES OF MANUFACTURER'S QUALITY MANAGEMENT SYSTEM, UNDER THE RESPONSIBILITY OF RAQ.
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 Date: 19/12/2023
NAME, JOB TITLE AND SIGNATURE	Alessandro Fiore Quality Assurance Manager (RAQ) Signature: 

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EC DECLARATION OF CONFORMITY

ANNEX I – LIST OF CODES

DEVICE CODE / CATALOGUE NUMBER	DEVICE NAME
2503105SAR	URINE CONTAINER 120 ml IN POLYPROPYLENE WITH GREEN SCREW CAP APART, WITH FROSTED LABEL (caps in bag of 100 pcs) (Art. 75.1354.001)
2503405SAR	URINE CONTAINER 120 ml IN POLYPROPYLENE WITH GREEN SCREW CAP, WITH FROSTED LABEL (Code 75.1354.002)
2503100SAR	URINE CONTAINER 120 ml IN POLYPROPYLENE WITH NEUTRAL SCREW CAP APART, WITH FROSTED LABEL (caps in bag of 100 pcs) (Code 75.1354.003)