



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	<b>CONTAINERS FOR BIOLOGICAL LIQUIDS COLLECTION</b>
DEVICE CODES	ref.: Annex I to the present Declaration of Conformity
RISK CLASS AND CLASSIFICATION RULE	<b>Risk class: Class A non-sterile</b> Classification rule: rule 5, according to Annex VIII of the Regulation 2017/746.
INTENDED PURPOSE	Collection of biological liquids for diagnostic testing
COMMON SPECIFICATIONS	<i>not applicable</i>
BASIC UDI-DI	8052109520004UD
NAME, ADDRESS AND IDENTIFICATION NUMBER OF THE NOTIFIED BODY	<i>not applicable</i>
CERTIFICATE NUMBER	<i>not applicable</i>
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	<i>not applicable</i>
<b>WE DECLARE UNDER OUR OWN RESPONSIBILITY THAT THE DEVICES ABOVE MENTIONED, OF WHICH RELATED CODES AND DESCRIPTIONS ARE ATTACHED, MEET THE PROVISIONS OF THE REGULATION 2017/746 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES. 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.</b>	
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: 14/07/2022
NAME, JOB TITLE AND SIGNATURE	Alessandro Fiore Quality Assurance Manager (RAQ)   Signature:



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### ANNEX I – LIST OF CODES

DEVICE CODE / CATALOGUE NUMBER	DEVICE NAME
25106GIM	URINE TANK 2500 ML IN POLYETHYLENE GRADUATED FOR 24 HOUR URINE COLLECTION IN SINGLE BOX "GIMA"
25103GIM	URINE CONTAINER 2500 ML IN POLYETHYLENE GRADUATED FOR 24 HOUR URINE COLLECTION
25108GIM	URINE TANK 2500 ML IN POLYETHYLENE GRADUATED FOR 24 HOUR URINE COLLECTION
25303GIM	24 H URINE COLLECTION CONTAINER 2000 ML IN POLYETHYLENE GRADUATED WITH ERGONOMIC HANDLE, CAPPED
25032GIM	URINE CONTAINER 120 ML IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL, INDIVIDUALLY WRAPPED (PRODUCED IN CLEANROOM ISO 8)
25132GIM	FAECES CONTAINER 30 ML IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL, INDIVIDUALLY WRAPPED (PRODUCED IN CLEANROOM ISO 8)
25162GIM	FAECES CONTAINER 60 ML IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL, INDIVIDUALLY WRAPPED (PRODUCED IN CLEANROOM ISO 8)
25182GIM	URINE CONTAINER 60 ML IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL, INDIVIDUALLY WRAPPED (PRODUCED IN CLEANROOM ISO 8)
25034GIM	URINE CONTAINER 120 ML IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL
25420	URINTAINER @ 24 H URINE COLLECTION CONTAINER 3000 ML IN POLYETHYLENE GRADUATED WITH ERGONOMIC HANDLE, BROWN COLOUR, CAP WITH COLLECTION DEVICE AND INTEGRATED STRAW FOR VACUUM TUBE