F.L. MEDICAL s.r.l. Unipersonale
Via Enrico Mattei, 20 – 35038 TORREGLIA (Padova) – Italy
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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

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 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: 26/05/2023
NAME, JOB TITLE AND SIGNATURE	Alessandro Fiore Quality Assurance Manager (RAQ) Signature: 

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ANNEX I – LIST OF CODES

Code	Description
25103	URINTAINER ® URINE CONTAINER 2500 ml IN POLYETHYLENE GRADUATED FOR 24 HOUR URINE COLLECTION
25012	URINTRANSFER ® SUCTION URINE CONTAINER 120 ml IN POLYPROPYLENE WITH YELLOW SCREW CAP, WITH PAPER LABEL, INDIVIDUALLY WRAPPED (Produced in cleanroom ISO 8)
25014	URINTRANSFER ® SUCTION URINE CONTAINER 120 ml IN POLYPROPYLENE WITH YELLOW SCREW CAP, WITH PAPER LABEL
2501402	URINTRANSFER ® SUCTION URINE CONTAINER 120 ml IN POLYPROPYLENE WITH LIGHT BLUE SCREW CAP, WITH PAPER LABEL
25030	URINTAINER ® URINE CONTAINER 120 ml IN POLYPROPYLENE WITH WHITE SCREW CAP APART, WITH FROSTED LABEL
25031	URINTAINER ® URINE CONTAINER 120 ml IN POLYPROPYLENE WITH RED SCREW CAP APART, WITH FROSTED LABEL
25032	URINTAINER ® URINE CONTAINER 120 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL, INDIVIDUALLY WRAPPED (Produced in cleanroom ISO 8)
25032E	URINTAINER ® URINE CONTAINER 120 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH PAPER LABEL, INDIVIDUALLY WRAPPED (Produced in cleanroom ISO 8)
25033	URINTAINER ® URINE CONTAINER 120 ml IN POLYPROPYLENE WITH WHITE SCREW CAP, WITH FROSTED LABEL
25034	URINTAINER ® URINE CONTAINER 120 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL
25034E	URINTAINER ® URINE CONTAINER 120 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH PAPER LABEL
25106	URINTAINER ® URINE TANK 2500 ml IN POLYETHYLENE GRADUATED FOR 24 HOUR URINE COLLECTION IN SINGLE BOX
25108	URINTAINER ® URINE TANK 2500 ml IN POLYETHYLENE GRADUATED FOR 24 HOUR URINE COLLECTION
25133	COPROTAINER ® FAECES CONTAINER 30 ml IN POLYPROPYLENE WITH WHITE SCREW CAP, WITH FROSTED LABEL
25134	COPROTAINER ® FAECES CONTAINER 30 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL
25170	URINTAINER ® URINE CONTAINER 30 ml IN POLYPROPYLENE WITH WHITE SCREW CAP APART, WITH FROSTED LABEL
25171	URINTAINER ® URINE CONTAINER 30 ml IN POLYPROPYLENE WITH RED SCREW CAP APART, WITH FROSTED LABEL
25172	URINTAINER ® URINE CONTAINER 30 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL, INDIVIDUALLY WRAPPED (Produced in cleanroom ISO 8)
25172E	URINTAINER ® URINE CONTAINER 30 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH PAPER LABEL, INDIVIDUALLY WRAPPED (Produced in cleanroom ISO 8)
25173	URINTAINER ® URINE CONTAINER 30 ml IN POLYPROPYLENE WITH WHITE SCREW CAP, WITH FROSTED LABEL

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25174	URINTAINER ® URINE CONTAINER 30 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL
25174E	URINTAINER ® URINE CONTAINER 30 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH PAPER LABEL
25181	URINTAINER ® URINE CONTAINER 60 ml IN POLYPROPYLENE WITH RED SCREW CAP APART, WITH FROSTED LABEL
25182	URINTAINER ® URINE CONTAINER 60 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL, INDIVIDUALLY WRAPPED (Produced in cleanroom ISO 8)
25182E	URINTAINER ® URINE CONTAINER 60 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH PAPER LABEL, INDIVIDUALLY WRAPPED (Produced in cleanroom ISO 8)
25183	URINTAINER ® URINE CONTAINER 60 ml IN POLYPROPYLENE WITH WHITE SCREW CAP, WITH FROSTED LABEL
25184	URINTAINER ® URINE CONTAINER 60 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
45030	VACUMED ® STRAW WITH COLLECTION DEVICE FOR URINE, LENGHT 9 cm
45035	VACUMED ® STRAW WITH COLLECTION DEVICE FOR URINE, LENGHT 17 cm