




F.L. MEDICAL s.r.l. Unipersonale
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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	TEST TUBES FOR BIOLOGICAL LIQUIDS COLLECTION
DEVICE CODES	ref.: Annex I to the present Declaration of Conformity
RISK CLASS AND CLASSIFICATION RULE	Risk class: Class A non-sterile Classification rule: rule 5, according to Annex VIII of the Regulation 2017/746.
INTENDED PURPOSE	Biological liquids collection for diagnostic testing
COMMON SPECIFICATIONS	<i>not applicable</i>
BASIC UDI-DI	8052109520003UB
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>
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.	
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: 26/07/2022
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
23056	EASY-LOCK® MICROTUBE 0,5 ML CONICAL IN POLYPROPYLENE WITH FLAT CAP AND FROSTED LABEL, GRADUATED, NEUTRAL COLOUR
23053	EASY-LOCK® MICROTUBE 1,5 ml CONICAL IN POLYPROPYLENE WITH FLAT CAP AND FROSTED LABEL, GRADUATED, NEUTRAL COLOUR
23073	EASY-LOCK® MICROTUBE 2 ml IN POLYPROPYLENE WITH FLAT CAP AND FROSTED LABEL, GRADUATED, NEUTRAL COLOUR
21401	PROMED® TEST TUBE 30x115 mm 50 ml CONICAL IN POLYPROPYLENE LIGHT BLUE SCREW CAP GRADUATED
21403	PROMED® TEST TUBE 30x115 mm 50 ml CONICAL IN POLYPROPYLENE LIGHT BLUE SCREW CAP GRADUATED WITH SELF-STANDING BASE
21408	PROMED® TEST TUBE 17x120 mm 15 ml CONICAL IN POLYPROPYLENE LIGHT BLUE SCREW CAP GRADUATED