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	**Test tubes 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	Test tubes intended for biological liquids collection
COMMON SPECIFICATIONS	*not applicable*
BASIC UDI-DI	8052109520003UB
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: *25/08/2022*
NAME, JOB TITLE AND SIGNATURE	Alessandro Fiore Quality Assurance Manager (RAQ) Signature: 

Digitally signed by Chirtoacă Iurie
Date: 2022.09.10 17:00:53 EEST
Reason: MoldSign Signature
Location: Moldova

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ANNEX I – LIST OF CODES

DEVICE CODE / CATALOGUE NUMBER	DEVICE NAME
22634	SEPARMED ® TECH TEST TUBE 13x75 mm IN POLYPROPYLENE WITH SEPARATING GRANULES WHITE STOPPER AND LABEL
22626	SEPARMED ® TECH TEST TUBE 12x86 mm IN POLYPROPYLENE WITH SEPARATING GRANULES WHITE STOPPER AND LABEL
22634	SEPARMED ® TECH TEST TUBE 13x75 mm IN POLYPROPYLENE WITH SEPARATING GRANULES WHITE STOPPER AND LABEL
22626	SEPARMED ® TECH TEST TUBE 12x86 mm IN POLYPROPYLENE WITH SEPARATING GRANULES WHITE STOPPER AND LABEL
22602	SEPARMED ® TECH TEST TUBE 16x100 mm IN POLYPROPYLENE WITH SEPARATING GRANULES WHITE STOPPER AND LABEL
22626	SEPARMED ® TECH TEST TUBE 12x86 mm IN POLYPROPYLENE WITH SEPARATING GRANULES WHITE STOPPER AND LABEL
21027	PROMED ® TEST TUBE 16x100 mm 10 ml CONICAL, WITHOUT RIM, GRADUATED, IN POLYPROPYLENE
21017	PROMED ® TEST TUBE 16x100 mm 10 ml CONICAL, WITH RIM, GRADUATED, IN POLYPROPYLENE
22744	SEPARMED ® TECH TEST TUBE 13x75 mm IN POLYPROPYLENE WITH SEPARATING GEL + COAGULATION ACCELERATOR RED STOPPER AND LABEL
22734	SEPARMED ® TECH TEST TUBE 12x86 mm IN POLYPROPYLENE WITH SEPARATING GEL + COAGULATION ACCELERATOR RED STOPPER AND LABEL
32107	PROMED ® TEST TUBE 12x56 mm WITH K3 EDTA x 2,5 ml OF BLOOD VIOLET STOPPER
32109	PROMED ® TEST TUBE 13x75 mm WITH K3 EDTA x 2,5 ml OF BLOOD VIOLET STOPPER
32116	PROMED ® TEST TUBE 13x75 mm WITH K3 EDTA x 4 ml OF BLOOD VIOLET STOPPER
22213	PROMED ® TEST TUBE 12x56 mm WITH 0,25 ml OF SODIUM CITRATE (3,8 %) PINK STOPPER FOR 1 ml OF BLOOD (ESR) AND 2,25 ml OF BLOOD (Coagulation)