F.L. MEDICAL s.r.l. Unipersonale
Via Enrico Mattei, 20 – 35038 TORREGLIA (Padova) – Italy
Tel. +39 049 5211475 / +39 049 5212835 - Fax +39 049 5212566
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

EC 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	*Sterile test tubes for biological liquids collection*
DEVICE CODES	**ref.: Annex I to the present Declaration of Conformity**
RISK CLASS AND CLASSIFICATION RULE	**Other type of IVD** IVD not included in Annex II of Directive 98/79/EC, nor self-testing IVD
INTENDED USE	*Test tubes for biological liquids collection, for diagnostic test*
COMMON SPECIFICATIONS	*not applicable*
BASIC UDI-DI	*not applicable*
NAME, ADDRESS AND IDENTIFICATION NUMBER OF THE NOTIFIED BODY	*not applicable*
CERTIFICATE NUMBER	*not applicable*
CONFORMITY ASSESSMENT PROCEDURE	Preparation of the technical documentation (ref. Annex III of Directive 98/79/EC) and issue of the EC 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: 24/05/2022
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
44970	VACUMED ® 16x100 mm WITH BORIC ACID x 10 ml OF URINE, YELLOW CAP, STERILE
44971	VACUMED ® 16x100 mm WITH BORIC ACID x 10 ml OF URINE, WHITE CAP, STERILE