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 (urine and feces) 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: *01/09/2022*
NAME, JOB TITLE AND SIGNATURE	Alessandro Fiore Quality Assurance Manager (RAQ) Signature:

Digitally signed by Chirtoacă Iurie
Date: 2022.09.10 15:32:47 EEST
Reason: MoldSign Signature
Location: Moldova

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ANNEX I – LIST OF CODES

DEVICE CODE / CATALOGUE NUMBER	DEVICE NAME
25134	COPROTAINER ® FAECES CONTAINER 30 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL
25034	URINTAINER ® URINE CONTAINER 120 ml IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL