


## EU DECLARATION OF CONFORMITY

<b>MANUFACTURER'S NAME</b>	F.L. MEDICAL s.r.l. Unipersonale
<b>MANUFACTURER'S REGISTERED PLACE OF BUSINESS AND ADDRESS</b>	Via Enrico Mattei, 20 – 35038 Torreglia (PD) - Italy
<b>MANUFACTURER'S SINGLE REGISTRATION NUMBER (SRN)</b>	IT-MF-000013918
<b>DEVICE NAME / TRADE NAME</b>	<b>CONTAINERS FOR BIOLOGICAL LIQUIDS COLLECTION</b>
<b>DEVICE CODES</b>	ref.: Annex I to the present Declaration of Conformity
<b>RISK CLASS AND CLASSIFICATION RULE</b>	<b>Risk class: Class A non-sterile</b> Classification rule: rule 5, according to Annex VIII of the Regulation 2017/746.
<b>INTENDED PURPOSE</b>	Collection of biological liquids for diagnostic testing
<b>COMMON SPECIFICATIONS</b>	<i>not applicable</i>
<b>BASIC UDI-DI</b>	8052109520004UD
<b>NAME, ADDRESS AND IDENTIFICATION NUMBER OF THE NOTIFIED BODY</b>	<i>not applicable</i>
<b>CERTIFICATE NUMBER</b>	<i>not applicable</i>
<b>CONFORMITY ASSESSMENT PROCEDURE</b>	Preparation of the technical documentation (ref. Annexes II and III of Regulation 2017/746) and issue of the EU Declaration of Conformity.
<b>ADDITIONAL INFORMATION</b>	<i>not applicable</i>
<p><b>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.</b></p> <p><b>ALL THE SUPPORTING DOCUMENTATION IS RETAINED AT THE ARCHIVES OF MANUFACTURER'S QUALITY MANAGEMENT SYSTEM, UNDER THE RESPONSIBILITY OF RAQ.</b></p> <p><b>THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER.</b></p>	
<b>PLACE OF DOCUMENTATION STORAGE</b>	Via Enrico Mattei, 20 – 35038 Torreglia (PD) - Italy
<b>PLACE AND DATE OF ISSUE OF THE PRESENT DECLARATION</b>	Via Enrico Mattei, 20 – 35038 Torreglia (PD) - Italy Date: 30/06/2022
<b>NAME, JOB TITLE AND SIGNATURE</b>	Alessandro Fiore Quality Assurance Manager (RAQ)   Signature:



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Reg. Imp. di Padova n. 21695 - R.E.A. di Padova n. 187254

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### ANNEX I – LIST OF CODES

DEVICE CODE / CATALOGUE NUMBER	DEVICE NAME
25032	URINTAINER ® URINE CONTAINER 120 ML IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED 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
25130	COPROTAINER ® FAECES CONTAINER 30 ML IN POLYPROPYLENE WITH WHITE SCREW CAP APART, WITH FROSTED LABEL
25131	COPROTAINER ® FAECES CONTAINER 30 ML IN POLYPROPYLENE WITH RED SCREW CAP APART, WITH FROSTED LABEL
25132	COPROTAINER ® FAECES CONTAINER 30 ML IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL, INDIVIDUALLY WRAPPED (PRODUCED IN CLEANROOM ISO 8)
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
25160	COPROTAINER ® FAECES CONTAINER 60 ML IN POLYPROPYLENE WITH WHITE SCREW CAP APART, WITH FROSTED LABEL
25161	COPROTAINER ® FAECES CONTAINER 60 ML IN POLYPROPYLENE WITH RED SCREW CAP APART, WITH FROSTED LABEL
25162	COPROTAINER ® FAECES CONTAINER 60 ML IN POLYPROPYLENE WITH RED SCREW CAP, WITH FROSTED LABEL, INDIVIDUALLY WRAPPED (PRODUCED IN CLEANROOM ISO 8)
25163	COPROTAINER ® FAECES CONTAINER 60 ML IN POLYPROPYLENE WITH WHITE SCREW CAP, WITH FROSTED LABEL
25164	COPROTAINER ® FAECES CONTAINER 60 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