

F.L. MEDICAL s.r.l. Unipersonale

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DECLARATION OF CONFORMITY

| MANUFACTURER | F.L. Medical s.r.l. Unipersonale |
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| HEADQUARTERS | TORREGLIA (PD) Via Enrico Mattei, 20 |
| DEVICE | SEPARMED ® TECH TEST TUBE 13x75 mm IN POLYPROPYLENE WITH SEPARATING GEL + COAGULATION ACCELERATOR RED STOPPER AND LABEL |
| CODE | 22744 |
| REFERENCE QUALITY ASSESSMENT | Class A non-sterile, Rule 5, Annex VIII, IVDR |

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 LAWS IN FORCE 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 AND DATE OF CURRENT | TORREGLIA (PD) Via Enrico Mattei, 20 |
|--------------------------------|--------------------------------------|
| ISSUE | Date 4/08/2022 |
| PLACE OF DOCUMENTATION STORAGE | TORREGLIA (PD) Via Enrico Mattei, 20 |
| SIGNATURE | RAQ // |
| | Alessandro Fiore |