EU DECLARATION OF CONFORMITY

Code: MOL_DECO_SI1701_100I_MOLMOUSE_2-2_EN Date: 2024-03-19

The Manufacturer:

Manufacturer Name/Registered trade Name	**ALIFAX S.R.L.**
SRN number	**IT-MF-000030029**
Address	**Via Merano 30** **33045 NIMIS (UD)** **ITALY**

declares on his own responsibility that the following devices:

Product Name and Product Code	MOLECULAR MOUSE SYSTEM	SI 1701.100/I
	MOLECULAR MOUSE	SI 1701.900/I
Intended Purpose	MOLECULAR MOUSE SYSTEM is a multiplex Real-Time PCR device intended for clinical laboratory professional users for in vitro diagnostic procedures (IVD) to be used in combination with IVD MOLECULAR MOUSE cartridges containing specific reagents to detect multiple nucleic acid targets in processed biological samples. MOLECULAR MOUSE instrument uses a dedicated software to perform an amplification reaction of targeted nucleic acid sequences using multiplex Real-Time PCR. The software processes the raw data obtained from the instrument, provides qualitative results and emits a test report, after verification and/or validation by the user. MOLECULAR MOUSE software manages from one to six MOLECULAR MOUSE instruments plugged to a personal computer in which the MOLECULAR MOUSE software is installed. The software identifies and manages each instrument independently: it recognizes the cartridge identity, handles the analysis, collects and processes the raw data, stores the test analysis and finally generates the report. The specifications to perform the test, including the targets list and the criteria for data interpretation are specified by the single IVD MOLECULAR MOUSE cartridge. MOLECULAR MOUSE SYSTEM provides results to support the diagnosis and is intended for combined use with other clinical and analytical results within a diagnostic protocol defined and regulated by each specific laboratory.	
Basic UDI-DI	805604014SI1701.X00/ICS	
Risk Class	Class A, according to IVDR 746/2017	

comply with the Regulation (EU) 2017/746 related to the In Vitro Diagnostic Medical Devices [IVDR].

We declare also that the devices have been designed and manufactured in conformity to the Standards and European Directives below:

Standards	EN ISO 13485:2016/A11:2021: Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 14971:2019: Medical devices - Application of risk management to medical devices EN ISO 15223-1:2021: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied EN ISO 18113 -1:2011: In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) EN ISO 18113 -3:2011: Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use EN 62304:2006+A1:2015: Medical device software - Software life cycle processes EN 61326-1:2013; EN 61326-2-6:2013: Electrical equipment for measurement, control and laboratory use - EMC requirements

Common Specifications	IEC 62366-1:2015+A1:2020: Application of usability engineering to medical devices IEC TR 62366-2:2016: Guidance on the application of usability engineering to medical device IEC 61010-1:2010+A1:2016; IEC 61010-2-101:2018: Safety requirements for electrical equipment for measurement, control, and laboratory use
European Directives	Directive 2015/863/EU (RoHS3) Radio Equipment Directive 2014/53/UE and its harmonized standards Electromagnetic Compatibility (EMC) Directive 2014/30/EU and its harmonized standards Low Voltage Directive (LVD) Directive 2014/35/EU and its harmonized standards

The devices have been CE Marked as IVD Medical Devices according to Article 48 (10) of IVDR 746/2017.

Any change made to the devices without the prior consent of the Manufacturer will automatically void the present Declaration of Conformity.

Place and date of issue: *Nimis (Udine), 2024-03-19*

Name and function: *Camillo Galiano, Managing Director*

Signature: