EU DECLARATION OF CONFORMITY

The Manufacturer:

Manufacturer Name/Registered trade Name	**ALIFAX S.R.L.**
Address	**Via Merano 30** **33045 NIMIS (UD)** **ITALY**

declares on his own responsibility that the following device/s:

Product Name and Product Code	LATEX CONTROLS	SI 305.100-A / SI 305.102-A (6 TESTS)
		SI 305.300-A / SI 305.302-A (30 TESTS)
Intended Purpose	Latex Controls are intended for in-vitro diagnostic professional use only in the quantitative control of the calibration status of ALIFAX ESR line analyzers. The control is performed on three samples with different known turbidity values analyzed for transmittance related to ESR values.	
Basic UDI-DI	805604014SI305.X0X-A7S	
Risk Class	Class A, according to IVDR 746/2017	

comply with the General Safety and Performance Requirements of the Regulation 746/2017 related to the In Vitro Diagnostic Medical Devices (IVDR).

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

Harmonised 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) - Part 1: Terms, definitions and general requirements EN ISO 18113 -2:2011: In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
Technical Standards	IEC 62366-1:2015: Application of usability engineering to medical devices IEC TR 62366-2:2016: Guidance on the application of usability engineering to medical device

The devices have been CE Marked as IVD Medical Device/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 (UD), 19th May 2022

Name and function: Camillo Galiano, Managing Director

Signature:

ALIFAX s.r.l.
Managing Director
Camillo Galiano