EU DECLARATION OF CONFORMITY

Code: ESR_DECO_SIR20PN_ROLLER20_2-2_EN Date: 2024-09-05

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 device:

Product Name and Product Code	ROLLER 20	SI R20-PN
Intended Purpose	ROLLER 20 is an in vitro diagnostic automatic analyzer for the quantitative determination of Erythrocyte Sedimentation Rate (ESR) in human blood samples with EDTA from adult and pediatric patients with suspected inflammation. ROLLER 20 provides results to inform clinical management for serious and non-serious conditions that require further diagnostic investigations and evaluation of the clinical status. The physician performs his/her expert evaluation on the information provided by the analyzer thanks to his/ her professional knowledge, competence and skills as per the local law.	
Basic UDI-DI	805604014SIR20.195.804DA	
Risk Class	According to Regulation (EU) 2017/746 [IVDR]: Class A	

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

We declare also that the device has been designed and manufactured in conformity to the Standards and European Directives/Regulations 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 by the manufacturer - Part 1: General requirements 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 18113-3:2011: Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use IEC 62304:2006+A1:2015: Medical device software - Software life cycle processes IEC 62366-1:2015+A1:2020: Medical devices - Part 1: Application of usability engineering to medical devices IEC 61010-1:2010+A1:2016: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements IEC 61010-2-101:2018: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment IEC TR 62366-2:2016: Medical devices - Part 2: Guidance on the application of usability engineering to medical devices
Common Specifications	N/A
European Directives/Regulations	Directive 2011/65/EU (RoHS2) and subsequent amendments Regulation (EU) 1907/2006 (REACH)

	Electromagnetic Compatibility (EMC) Directive 2014/30/EU and its harmonized standards Low Voltage Directive (LVD) Directive 2014/35/EU and its harmonized standards

The device has been CE Marked as IVD Medical Device according to Article 48 (10) of IVDR 746/2017.

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

Place and date of issue: Nimis (Udine), 5th September 2024

Name and function: Camillo Galiano, Managing Director

Signature: