EU DECLARATION OF CONFORMITY

Code: MIC_DECO_SI190300_HB&L_2-0_EN Date: 2022-05-24

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 devices:

Product Name and Product Code	HB&L UROQUATTRO HB&L UROQUATTRO LIGHT	SI 190.300 SI 190.300L
Intended Purpose	Semi-Automated instrument for in vitro diagnostic procedures (IVD) intended for semi-quantitative detection of the growth of microorganisms in human liquid biological samples or bacterial suspensions using light-scattering technology.	
Basic UDI-DI	805604014SI190.300XFV	
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) 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
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 IEC 61010-1:2010+A1:2016; IEC 61010-2-101:2018: Safety requirements for electrical equipment for measurement, control, and laboratory use IEC 61326-2-6:2020: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
Other	Directive 2015/863/EU (RoHS3)

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

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), 24th May 2022

Name and function: Camillo Galiano, Managing Director

Signature: