EU DECLARATION OF CONFORMITY

Code: MOL_DECO_SI17010102_MMGRAMNEGID-1-0_EN.docx Date: 2022-05-23

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	MM GRAM NEG ID	SI 1701.0102
		SI 1701.0102/L
Intended Purpose	MM GRAM NEG ID is a qualitative in vitro diagnostic test, intended for professional clinical laboratory users, for the multiplex identification of nucleic acid sequences specific to Gram-negative bacteria starting from a positive blood culture of Gram-negative bacteria. The MM GRAM NEG ID cartridge contains all the necessary reagents to perform one single test through a multiplex Real Time PCR analysis in combination with MOLECULAR MOUSE SYSTEM. MM GRAM NEG ID analyzes the following targets: Pseudomonas aeruginosa, Acinetobacter baumannii, Neisseria meningitidis, Klebsiella aerogenes, Haemophilus influenzae, Proteus mirabilis, Enterobacteriaceae, Klebsiella oxytoca, Escherichia coli/Shigella sp, Salmonella typhi, Enterobacter cloacae, Stenotrophomonas maltophilia, Serratia marcescens, Klebsiella pneumoniae, Proteus spp. MM GRAM NEG ID provides a result to support the diagnosis of blood infection with Gram-negative microorganisms. The MM GRAM NEG ID test is intended for combined use with other clinical and analytical results within a diagnostic evaluation defined and regulated by each specific laboratory. MM GRAM NEG ID does not replace traditional methods based on culture testing. The result does not exclude the combined presence of targets other than those included in the list of identifiable targets for the identification of which other independent tests are necessary	
Risk Class	Other IVD Medical Device as it/they is/are neither in List A nor in List B of Annex II of the Directive 98/79/EC"	

complies with the Essential Requirements of the Directive 98/79/EC related to the In Vitro Diagnostic Medical Devices (IVDD).

We declare also that the device has been designed and manufactured in conformity to the below:

Harmonized 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 –Part1 : Terms, definitions and general requirements EN ISO 18113-2:2011: In vitro diagnostic medical devices - Information supplied by the manufacturer – Part 2: In vitro diagnostic reagents for professional use EN 13612:2002/AC:2002: Performance evaluation of in vitro diagnostic medical devices EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents

Technical Standards	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
Other	Directive 2015/863/EU (RoHS3) and subsequent amendments

The devices have been CE Marked as IVD Medical Device/Devices according to Annex III of the Directive 98/79/EC as they are neither in List A nor in List B of Annex II.

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), 2022-05-23

Name and function: Camillo Galiano, Managing Director

Signature: