EU DECLARATION OF CONFORMITY

Code: MOL_DECO_SI17010104_MMGRAMPOS_NOSTAPH-1-0_EN.docx Date: 2022-05-18

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	MM GRAM POS NO STAPH	SI 1701.0104 SI 1701.0104/L
Intended Purpose	MM GRAM POS NO STAPH is a qualitative in vitro diagnostic test, intended for professional clinical laboratory users, for the multiplex identification of nucleic acid sequences specific to Gram-positive other than Staphylococcus bacteria and/or nucleic acid sequences associated with their non-susceptibility to vancomycin, starting from a positive blood culture of Gram-positive bacteria. The MM GRAM POS NO STAPH cartridge contains all the necessary reagents to perform one single test through a Real Time PCR multiplex analysis in combination with MOLECULAR MOUSE SYSTEM. MM GRAM POS NO STAPH analyzes the following targets: Streptococcus agalactiae, Streptococcus pyogenes, Streptococcus pneumoniae, Enterocccus faecalis, Enterococcus spp, Enterococcus faecium, Streptococcus anginosus, Listeria monocytogenes, Bacillus subtilis, Streptococcus spp, Van A, Van B, Van C 1, Van C 2/3. The negative result for the targets Van A, Van C 1, Van B, Van C 2/3 does not exclude the presence of other drug resistance mechanisms. MM GRAM POS NO STAPH provides a result to support the diagnosis of blood infection with Gram-positive other than Staphylococcus microorganisms and/or their non-susceptibility to vancomycin. The MM GRAM POS NO STAPH 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 POS NO STAPH does not replace traditional methods based on culture and antibiotic susceptibility 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 devices have 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)

The device 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), 2022-05-18

Name and function: Camillo Galiano, Managing Director

Signature: