



# EU DECLARATION OF CONFORMITY

Code: MOL\_DECO\_SI17010101\_MMGRAMNEGRES-1-0\_EN.docx

Date:

2022-05-23

The Manufacturer:

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

declares on his own responsibility that the following devices:

<b>Product Name and Product Code</b>	MM GRAM NEG RES	SI 1701.0101
		SI 1701.0101/L
<b>Intended Purpose</b>	<p>MM GRAM NEG RES is a qualitative in vitro diagnostic test, intended for professional clinical laboratory users, for the multiplex identification of nucleic acid sequences known to be associated with non-susceptibility to beta lactam drugs (Carba /ESBL/AmpC) and colistin starting from positive blood culture of Gram-negative bacteria.</p> <p>The MM GRAM NEG RES cartridge contains all the necessary reagents to perform one single test through a multiplex Real Time PCR analysis in combination with MOLECULAR MOUSE SYSTEM.</p> <p>MM GRAM NEG RES analyses the following targets: KPC, VIM, NDM, IMP, OXA-23-like, OXA-48-like, SHV, SHV ESBL, CTX-M-1/9 groups, CTX-M-2/8 groups, CMY-2, mcr-1, mcr-2.</p> <p>The negative result does not exclude that other resistance mechanisms are present. MM GRAM NEG RES provides a result to support the diagnosis of blood infection with Gram-negative microorganisms.</p> <p>The MM GRAM NEG RES 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 RES does not replace traditional methods based on antibiotic susceptibility testing. culture</p> <p>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.</p>	
<b>Risk Class</b>	Other IVD Medical Device as they are neither in List A nor in List B of Annex II of the Directive 98/79/EC"	

comply 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:

<b>Harmonized Standards</b>	<p>EN ISO 13485:2016/A11:2021: Medical devices - Quality management systems - Requirements for regulatory purposes</p> <p>EN ISO 14971:2019: Medical devices - Application of risk management to medical devices</p> <p>EN ISO 15223-1:2021: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied</p> <p>EN ISO 18113-1:2011: In vitro diagnostic medical devices - Information supplied by the manufacturer –Part1 : Terms, definitions and general requirements</p> <p>EN ISO 18113-2:2011: In vitro diagnostic medical devices - Information supplied by the manufacturer – Part 2: In vitro diagnostic reagents for professional use</p> <p>EN 13612:2002/AC:2002: Performance evaluation of in vitro diagnostic medical devices</p>
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	EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
<b>Technical Standards</b>	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
<b>Other</b>	Directive 2015/863/EU (RoHS3)

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, 2022-05-23**

**Name and function: Camillo Galiano, Managing Director**

**Signature:**



**ALIFAX S.r.l.**  
Managing Director  
Camillo Galiano