

Certificat/Certificate: N° 39239 rev. 1

Délivré le /Issued on: July 7th, 2023

Certificat délivré à /Certificate issued to: **BIOMERIEUX S.A.**

376, Chemin de l'Orme

69280 MARCY L ETOILE FRANCE

SRN: FR-MF-000004436

GMED atteste qu'à l'examen des résultats figurant sur le(s) rapport(s) d'audit du système de gestion de la qualité référencé(s) P602831, le système de gestion de la qualité est conforme aux dispositions pertinentes du règlement (UE) 2017/746 pour les produits suivants :

GMED certifies that, on the basis of the results contained in the quality management system audit report(s) referenced P602831, the quality management system complies with the relevant provisions of the regulation (EU) 2017/746 for the following products:

Dispositifs médicaux de diagnostic in vitro : trousse, réactifs et matériaux de contrôles destinés à être utilisés pour détecter la présence d'un agent infectieux ou l'exposition à un tel agent, y compris les agents sexuellement transmissibles.

In vitro diagnostic medical devices: kits, reagents and control materials intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmissible agents.

Voir détails sur addendum / See addendum for additional information

Aux fins de la mise sur le marché de dispositifs de diagnostic in vitro de classe C (près du patient, autodiagnostic ou diagnostic compagnon) et/ou de classe D, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/746 est requis.

For the purpose of placing on the market class C in vitro diagnostic devices (devices for self-testing, near patient testing or companion diagnostics) and / or class D, another certificate issued in accordance with the provisions of Regulation (EU) 2017/746 is required.

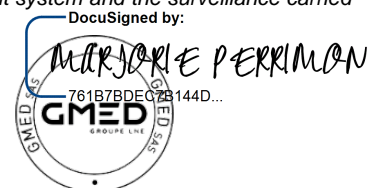
Début de validité /Effective date: July 7th, 2023 (included)

Valable jusqu'au /Expiry date: April 5th, 2027 (included)

La validité du présent certificat est conditionnée au respect des obligations qui découlent du système de gestion de la qualité approuvé et de la surveillance effectuée par l'organisme notifié prévue par le règlement. Ce certificat est lié par les conditions du contrat.

The validity of this certificate is subject to compliance with the obligations arising from the approved quality management system and the surveillance carried out by the notified body as required by the regulation. This certificate is bound by the conditions of the contract.

DocuSigned by:
MARJORIE PERRIMON
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On behalf of the President
Marjorie PERRIMON
Certification Director

1. Le cas échéant, le nom et l'adresse du mandataire / If applicable, the name and address of the authorised representative:

Non applicable / Non applicable

2. Identification des sites / Identification of sites:

BIOMERIEUX S.A. - 376 Chemin de l'Orme - 69280 MARCY L'ETOILE - FRANCE

BIOMERIEUX S.A. - 5 rue des Berges - 38024 GRENOBLE CEDEX 01 - FRANCE

BIOMERIEUX S.A. - Avenue des Bergeries - 01150 SAINT VULBAS - FRANCE

BIOMERIEUX S.A. - 138 rue Louis Pasteur - Parc Technologique Delta Sud - 09340 VERNIOLLE - FRANCE

3. Identification des dispositifs / Identification of devices:

Nom commercial <i>Commercial name</i>	Références commerciales <i>Commercial references</i>	Destination <i>Intended use</i>	Classe du DM DIV IVD MD Class	Référence aux autres certificats requis pour la mise sur le marché <i>Reference to other certificates required for placing on the market</i>
COVID-19 R-GENE®	424017	The COVID-19 R-GENE® kit allows a qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), responsible for coronavirus disease 2019 (COVID-19), in nasopharyngeal swabs and saliva. The COVID-19 R-GENE® kit detects specifically SARS-CoV-2 (targeting both RdRp and N genes), and an endogenous internal control. Detection is based on real-time PCR using the 5' nuclease technique. The kit is intended for the qualitative detection of SARS-CoV-2 in individuals who are suspected of COVID-19 infection by a healthcare provider. The results are indicative of detection or non-detection of SARS-CoV-2 RNA, and should be combined with clinical signs, patient history and epidemiological information for patient management decisions.	D	39244

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On behalf of the President
Marjorie PERRIMON
Certification Director


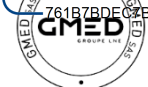
Nom commercial <i>Commercial name</i>	Références commerciales <i>Commercial references</i>	Destination <i>Intended use</i>	Classe du DM DIV IVD MD Class	Référence aux autres certificats requis pour la mise sur le marché <i>Reference to other certificates required for placing on the market</i>
SARS-COV-2 / FLUA / FLUB / RSV R-GENE®	424433	<p>The SARS-COV-2/FLUA/FLUB/RSV R-GENE® kit allows a qualitative detection and differentiation of SARS-CoV-2, Influenza A, Influenza B, Respiratory Syncytial Virus (RSV) and an endogenous internal control, in nasopharyngeal swabs. Detection is based on the real-time PCR technology after extraction of the viral RNA.</p> <p>The kit is intended as an aid to the diagnosis in individuals who are suspected of those respiratory infections by a healthcare provider. The results are indicative of the detection or non-detection of SARS-CoV-2, Influenza A, Influenza B and RSV RNA, and should be combined with clinical signs, patient history and epidemiological information for patient management.</p> <p>This kit is intended for in vitro diagnostic use only, in clinical laboratories by laboratory health professionals.</p>	D	39344

4. Historique du certificat / Certificate history:

Référence au certificat précédent <i>Reference to the previous certificate</i>	Date de délivrance <i>Date of issue</i>	Modifications apportées <i>Identification of the changes</i>
39239 rev. 0	24/02/2023 2023/02/24	Ajout de référence / <i>Addition of reference</i> SARS-COV-2 / FLUA / FLUB / RSV R-GENE® Ref. 424433

5. Le cas échéant, les informations spécifiques relatives aux limitations de la validité du certificat / If applicable, specific information relating to the limitations to the validity of the certificate : Non applicable / *Non applicable*

6. Le cas échéant, les informations spécifiques relatives à la surveillance effectuée dans le cadre du maintien du certificat / If applicable, specific information relating to the surveillance carried out in the context of maintaining the certificate : Non applicable / *Non applicable*

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On behalf of the President
Marjorie PERRIMON
Certification Director