CERTIFICAT UE DE SYSTEME DE GESTION DE LA QUALITE
Règlement (UE) 2017/746, Annexe IX chapitres I et III

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/746, Annex IX chapters I and III

Certificat/*Certificate:* N° 39239 rev. 5

Délivré le/*Issued on:* March 18th, 2024

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 dans le(s) rapport(s) d'audit du système de gestion de la qualité et le(s) rapport(s) d'évaluation de la documentation technique associé(s), le cas échéant, 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 listed in the quality management system audit report(s) and the associated technical documentation assessment report, where appropriate, 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 : trousses, 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 D, de diagnostics compagnons de classe C et de dispositifs de diagnostic in vitro d'autodiagnostic et de diagnostic près du patient de classe B et C, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/746 est requis. 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.

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

Début de validité */Effective date:* March 18th, 2024 (included)

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

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Beatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director

GMED - 39239 rev. 5
Modifie le certificat 39239-4

720 RDM 0701-98 rev 3 du 29/JAN/2024

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 *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*	Référence aux autres certificats requis pour la mise sur le marché *Reference to other certificates required for placing on the market*
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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Béatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • RCS Paris 839 022 522 • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • lne-gmed.com

Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*	Référence aux autres certificats requis pour la mise sur le marché *Reference to other certificates required for placing on the market*
SARS-COV-2 / FLUA / FLUB / RSV R-GENE®	424433	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. 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. This kit is intended for in vitro diagnostic use only, in clinical laboratories by laboratory health professionals.	D	39344
VIDAS® Anti-HBs Total II	30318	VIDAS® Anti-HBs Total II is an automated quantitative test for use on the VIDAS® family of instruments, for the immunoenzymatic detection of antibodies to hepatitis B surface antigen (Anti HBs) in human serum or plasma using the ELFA technique (Enzyme Linked Fluorescent Assay). The assay is intended for screening of immune status against HBV in general adult population, to help to determine: - Vaccination status - Recovery of previous HBV infection (natural immunity)	D	39415
VIDAS® SARS-COV-2 IgG QUANT	424422	VIDAS® SARS-COV-2 IgG QUANT (COGQ) is an automated quantitative assay for use on the VIDAS® family of instruments, for the detection and the measurement of the concentration of immunoglobulin G (IgG) specific for the SARS-CoV-2 receptor-binding domain (RBD) of the spike protein in human serum or plasma (lithium heparin) using the ELFA (Enzyme Linked Fluorescent Assay) technique.	D	39508

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Technical Director

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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*	Référence aux autres certificats requis pour la mise sur le marché *Reference to other certificates required for placing on the market*
VIDAS® HBs Ag Ultra	30315	VIDAS® HBs Ag Ultra (HBS) is an automated qualitative test for use on the VIDAS® family instruments for the detection of hepatitis B surface antigen (HBs Ag) in human serum or plasma, using the ELFA technique (Enzyme Linked Fluorescent Assay). This assay is intended to be used as an aid in the diagnosis of hepatitis B infection (either acute or chronic) and for the screening of hepatitis B infection in general adult population.	D	39541
VIDAS® HBs Ag Ultra Confirmation	30317	Supplementary VIDAS® HBs Ag Ultra is intended to be used to confirm the presence of HBsAg in the screened population and to diagnose hepatitis B infection (either acute or chronic) in general adult population. The VIDAS® HBs Ag Ultra Confirmation test is used in conjunction with the VIDAS® HBs Ag Ultra screening test ref. 30315. It enables confirmation of a repeatedly positive result obtained using VIDAS® HBs Ag Ultra	D	39641

4. Historique du certificat / *Certificate history:*

Référence au certificat précédent *Reference to the previous certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
39239 rev. 0	24/02/2023 *02/24/2023*	Ajout de référence / *Addition of reference* SARS-COV-2 / FLUA / FLUB /RSV R-GENE® - Ref. 424433
39239 rev. 1	07/07/2023 *07/07/2023*	Ajout de référence / *Addition of reference* VIDAS® Anti-HBs Total II - Ref. 30318
39239 rev. 2	04/10/2023 *10/04/2023*	Ajout de référence / *Addition of reference* VIDAS® SARS-COV-2 IgG QUANT - Ref 424422
39239 rev. 3	21/12/2023 *12/21/2023*	Ajout de référence / *Addition of reference* VIDAS® HBs Ag Ultra - Ref 30315
39239 rev. 4	25/01/2024 01/25/2024	Ajout de référence / *Addition of reference* VIDAS® HBs Ag Ultra Confirmation - Ref 30317

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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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