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. 11

Délivré le/*Issued on:* July 18th, 2025

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:* July 18th, 2025 (included)

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

Signed by:
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On behalf of the President
Béatrice LYS
Technical Director

GMED - 39239 rev. 11
Modifie le certificat 39239-10

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 du dispositif *Device trade name*	Références commerciales du dispositif *Device Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*	Référence au certificat requis pour la mise sur le marché du dispositif *Reference to the certificate required for placing on the market the device*
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
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 du dispositif *Device trade name*	Références commerciales du dispositif *Device Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*	Référence au certificat requis pour la mise sur le marché du dispositif *Reference to the certificate required for placing on the market the device*
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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Nom commercial du dispositif *Device trade name*	Références commerciales du dispositif *Device Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*	Référence au certificat requis pour la mise sur le marché du dispositif *Reference to the certificate required for placing on the market the device*
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
VIDAS® HIV Duo Quick	30447	VIDAS® HIV DUO Quick is an automated qualitative HIV infection screening test for use on the VIDAS® family instruments, for the combined detection of anti-HIV-1 (groups M and O) and anti-HIV-2 total immunoglobulins and HIV-1 p24 antigen in human serum or plasma (lithium heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay). VIDAS® HIV DUO Quick is intended for use in screening in populations eligible for HIV testing including: • General population (adults/adolescents with average risk) • Children above 18 months • At risk population (key populations/vulnerable groups) • Pregnant women	D	39686

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Nom commercial du dispositif *Device trade name*	Références commerciales du dispositif *Device Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*	Référence au certificat requis pour la mise sur le marché du dispositif *Reference to the certificate required for placing on the market the device*
VIDAS® HIV Duo Ultra	30443	VIDAS® HIV DUO Ultra is an automated qualitative HIV infection screening test for use on the VIDAS® family instruments, for the combined detection of anti-HIV-1 (groups M and O) and anti-HIV-2 total immunoglobulins and HIV-1 p24 antigen in human serum or plasma (lithium heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay). VIDAS® HIV DUO Ultra is intended for use in screening in populations eligible for HIV testing including: • General population (adults/adolescents with average risk) • Children above 18 months • At risk population (key populations/vulnerable groups) • Pregnant women	D	39690
VIDAS® Anti-HCV	30308	VIDAS® Anti-HCV is an automated qualitative assay for use on the VIDAS® family of instruments, for the detection of IgG antibodies to hepatitis C virus (anti-HCV) in human serum or plasma (heparin) using the ELFA (Enzyme Linked Fluorescent Assay) technique. The detection of these specific antibodies, in conjunction with other clinical information, is intended to be used as an aid in the diagnosis and screening of hepatitis C infection in general adult population.	D	39946
VIDAS® HIV DUO AG/AB	424480	VIDAS® HIV DUO AG/AB (HIV) is an automated qualitative assay for use on the VIDAS® family instruments, for the combined detection of anti-HIV-1 (groups M and O) and anti-HIV-2 total immunoglobulins and HIV-1 p24 antigen in human serum or plasma (lithium heparin or EDTA) using the ELFA (Enzyme Linked Fluorescent Assay) technique. VIDAS® HIV DUO AG/AB is intended to be used as an aid in diagnosis of patients with acute or chronic HIV infections, and for screening of general adult populations, including pregnant women.	D	40048

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VIDAS® HBc IgM II	30439	VIDAS® HBc IgM II is an automated quantitative test for use on the VIDAS® family instruments for the determination of anti-hepatitis B virus core antigen IgM (anti-HBc IgM) in human serum or plasma (EDTA, citrate and lithium heparin), using the ELFA technique (Enzyme Linked Fluorescent Assay). Combined with total anti-HBc antibody testing, the detection of anti-HBc IgM antibody is intended to be used as an aid in diagnosis of hepatitis B virus infection in general adult population with suspected hepatitis B infection.	D	40238
VIDAS® HBe / Anti-HBe (HBE/HBET)	30305	VIDAS® HBe / Anti-HBe is an automated qualitative test for use on the VIDAS® family instruments, for the detection of the hepatitis B e-antigen (HBe Ag) or antibodies (anti-HBe) in human serum or plasma (lithium heparin, sodium citrate or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay). It is intended to be used as an aid in diagnosis of hepatitis B infection (either acute or chronic) in general adult population.	D	40268

*mentionnée par le fabricant dans la notice d'utilisation / *as included by the manufacturer in the instructions for use*

4. Historique du certificat / *Certificate history:*

Version du certificat *Version of the certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
39239 rev. 0	24/02/2023 *02/24/2023*	NA : création / *NA: creation*
39239 rev. 1	07/07/2023 *07/07/2023*	Ajout de référence / *Addition of reference* SARS-COV-2 / FLUA / FLUB /RSV R-GENE® - Ref. 424433

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On behalf of the President
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Version du certificat *Version of the certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
39239 rev. 2	04/10/2023 *10/04/2023*	Ajout de référence / *Addition of reference* VIDAS® Anti-HBs Total II - Ref. 30318
39239 rev. 3	21/12/2023 *12/21/2023*	Ajout de référence / *Addition of reference* VIDAS® SARS-COV-2 IgG QUANT - Ref. 424422
39239 rev. 4	25/01/2024 *01/25/2024*	Ajout de référence / *Addition of reference* VIDAS® HBs Ag Ultra - Ref. 30315
39239 rev. 5	18/03/2024 *03/18/2024*	Ajout de référence / *Addition of reference* VIDAS® HBs Ag Ultra Confirmation - Ref. 30317
39239 rev. 6	16/04/2024 *04/16/2024*	Ajout de référence / *Addition of reference* VIDAS® HIV Duo Ultra - Ref. 30443 VIDAS® HIV Duo Quick - Ref. 30447
39239 rev. 7	19/07/2024 *07/19/2024*	Ajout de référence / *Addition of reference* VIDAS® Anti-HCV - Ref. 30308
39239 rev. 8	21/10/2024 *10/21/2024*	Ajout de référence / *Addition of reference* VIDAS® HIV DUO AG/AB (Ref. 424480)
39239 rev. 9	18/11/2024 *11/18/2024*	Correction erreur typographique *Correction of typographical error*
39239 rev. 10	06/06/2024 *06/06/2024*	Ajout de référence / *Addition of reference* VIDAS® HBc IgM II (Ref. 30439)
39239 rev. 11	18/07/2025 *07/18/2025*	Ajout de référence / *Addition of reference* VIDAS® HBe / Anti-HBe (HBE/HBET) - (Ref. 30305)

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

6. **Le cas échéant, les informations spécifiques relatives à la surveillance effectuée par l'organisme notifié /** *If applicable, specific information about the surveillance carried out by the notified body:* Non applicable / *Non applicable*

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