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° 38815 rev. 10

Délivré le/*Issued on:* January 30th, 2026

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 - P604662 - P604666 - P604668, 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 - P604662 - P604666 - P604668, 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:* January 30th, 2026 (included)

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

Signé par :

GMED

On behalf of the President
Béatrice LYS
Technical Director

GMED - 38815 rev. 10
Modifie le certificat 38815-9

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
BIOMERIEUX S.A. - 5 rue des Aqueducs - 69290 CRAPONNE - FRANCE
BIOMERIEUX S.A. - 3 route de Port Michaud - 38390 LA BALME LES GROTTES - FRANCE
BIOMERIEUX S.A. - 4 bis, rue des Coutures - 35270 COMBOURG - FRANCE

3. **Identification des dispositifs /** *Identification of devices:*

Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
VIDAS® Anti-HAV Total	30312	VIDAS® Anti-HAV Total (HAVT) is an automated test for use on the VIDAS® family instruments for the quantitative measurement of total immunoglobulins directed against the hepatitis A virus (HAV) in human serum or plasma (lithium heparin EDTA and Citrate), using the ELFA technique (Enzyme Linked Fluorescent Assay). Combined with VIDAS® HAV IgM, the detection of total immunoglobulins directed against the hepatitis A virus (HAV) with VIDAS® Anti-HAV Total is used for screening of HAV immune status (related to past infection or vaccination) and is an aid in diagnosis of hepatitis A infection in patients with symptoms and/or clinical signs of hepatitis A.	B

Signé par :
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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 *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
VIDAS® Anti-HEV IgG	418116	VIDAS® Anti-HEV IgG (HEVG) is an automated quantitative test for use on the VIDAS® family of instruments for the detection of IgG antibody to hepatitis E virus in human serum and plasma, using the ELFA technique (Enzyme Linked Fluorescent Assay). VIDAS® Anti-HEV IgG is intended for use as a complement to the VIDAS® Anti-HEV IgM assay, to aid in the diagnosis of hepatitis E infection in patients with symptoms and/or clinical signs of hepatitis.	B
Rhino&EV/Cc R-GENE®	71-042	The Rhino&EV/Cc R-GENE® kit allows a qualitative detection of Enterovirus and Rhinovirus without distinction using the real time RT-PCR technology after extraction of the viral RNA in nasopharyngeal aspirate, nasopharyngeal swab and bronchoalveolar lavage. A cellular control (Cc) included in the kit evaluates the quality of sample collection by validating the presence of cells. Combined with other Clinical and Diagnostic Investigations, the results obtained with Rhino&EV/Cc R-GENE® are an aid to the diagnosis of Rhinovirus and Enterovirus in patients with an indication for these targets testing. This kit is intended for in vitro diagnostic use only, in clinical laboratories by laboratory health professionals.	B
VIDAS® EBV EBNA IgG	30235	VIDAS® EBV EBNA IgG is an automated test for use on the VIDAS® family instruments, for the qualitative detection of anti-EBNA IgG in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). Detection of these specific antibodies is an aid in diagnosing infectious mononucleosis (IM).	B
VIDAS® EBV VCA/EA IgG	30236	VIDAS® EBV VCA/EA IgG is an automated test for use on the VIDAS® family instruments, for the qualitative detection of anti-VCA and anti-EA IgG in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). Detection of these specific antibodies is an aid in diagnosing infectious mononucleosis (IM).	B
VIDAS® EBV VCA IgM	30237	VIDAS® EBV VCA IgM is an automated test for use on the VIDAS® family instruments, for the qualitative detection of anti-VCA IgM in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). Detection of these specific antibodies is an aid in diagnosing infectious mononucleosis (IM).	B
VIDAS® HAV IgM	30307	VIDAS® HAV IgM is an automated qualitative test for use on the VIDAS® family instruments for the detection of IgM directed against the hepatitis A virus (HAV) after immunocapture, in human serum or plasma (heparin or EDTA), using the ELFA technique (Enzyme Linked Fluorescent Assay). The detection of IgM antibodies directed against the hepatitis A virus (HAV) with VIDAS® HAV IgM test is an aid in diagnosis of acute hepatitis A infection in patients with symptoms and/or clinical signs of hepatitis A.	B

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VIDAS® Lyme IgM	30319	The VIDAS® Lyme IgM (LYM) (ref. 30 319) assay is an automated qualitative test intended for use on the VIDAS® family of instruments, for the detection of IgM antibodies to Borrelia burgdorferi sensu lato (sl) in human serum or plasma, to aid in the diagnosis of Lyme disease. The principle of detection of the VIDAS® Lyme IgM and VIDAS® Lyme IgG assays is based on the ELFA (Enzyme Linked Fluorescent Assay) technique.	B
VIDAS® Lyme IgG	30320	The VIDAS® Lyme IgG (LYG) (ref. 30 320) assay is an automated qualitative test intended for use on the VIDAS® family of instruments, for the detection of IgG antibodies to Borrelia burgdorferi sensu lato (sl) in human serum or plasma, to aid in the diagnosis of Lyme disease. The VIDAS® Lyme IgG (LYGS) (ref. 30 320) assay is an automated qualitative test intended for use on the VIDAS® family of instruments, for the detection of IgG antibodies to Borrelia burgdorferi sensu lato (sl) in cerebrospinal fluid (CSF), in order to determine intrathecal antibody production, to aid in the diagnosis of neuroborreliosis. The principle of detection of the VIDAS® Lyme IgM and VIDAS® Lyme IgG assays is based on the ELFA (Enzyme Linked Fluorescent Assay) technique.	B
VIDAS® Anti-DENGUE IgM	423078	VIDAS® Anti-DENGUE IgM is an automated qualitative test for use on the VIDAS® family of instruments. It is intended for the detection of IgM antibodies to dengue virus in human serum, using the ELFA technique (Enzyme Linked Fluorescent Assay). It is an aid in the diagnosis of patients with clinical symptoms consistent with dengue infection.	B
VIDAS® Anti-DENGUE IgG	423079	VIDAS® Anti-DENGUE IgG is an automated qualitative test for use on the VIDAS® family of instruments. It is intended for the detection of IgG antibodies to dengue virus in human serum, using the ELFA technique (Enzyme Linked Fluorescent Assay). It is an aid in the diagnosis of patients with clinical symptoms consistent with dengue infection.	B
VIDAS® C. difficile Toxin A & B	30118	The VIDAS® C. difficile Toxin A & B (CDAB) Assay is an automated test for use on the VIDAS® family instruments for the qualitative detection of Clostridium difficile toxin A and toxin B in stool specimens using the ELFA technique (Enzyme-Linked Fluorescent Assay). The VIDAS® C. difficile toxin A & toxin B (CDAB) assay is an aid for diagnosing Clostridium difficile associated disease (CDAD).	B

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VIDAS® C. difficile GDH	30125	VIDAS® C. difficile GDH (GDH) is an automated test based on the Enzyme Linked Fluorescent Assay technique (ELFA), for use on the VIDAS family of instruments. The VIDAS C. difficile GDH (glutamate dehydrogenase) assay is a qualitative test that detects the C. difficile antigen, glutamate dehydrogenase, as a screen for the presence of C. difficile in fecal specimens from persons suspected of having C. difficile infection (CDI). With the use of additional tests that detect C. difficile toxins, the test is to be used as an aid in the diagnosis of C. difficile infection. As with other C. difficile tests, results should be considered in conjunction with the patient history.	B
HHV6 R-GENE®	69-006B	The HHV6 R-GENE® kit, using the real-time PCR technology after extraction of the viral DNA, enables to detect and/or quantify the genome of HHV-6 in whole blood, plasma, cerebrospinal fluid (CSF)and bronchoalveolar lavage (BAL) samples. Combined with other biological investigation methods (medical imaging, biochemical and immunological analysis, etc.), the results obtained with the HHV6 R-GENE® kit are an aid to the diagnosis and monitoring of HHV-6 infections (primary infections or reactivations) in patients at risk or showing pathological condition suggesting an HHV-6 infection. This kit is intended for in vitro diagnostic use only, in clinical laboratories by laboratory health professionals.	C
HSV1 HSV2 R-GENE®	71-021	The HSV1 HSV2 R-GENE® kit, using the real-time PCR technology after extraction of the viral DNA, enables the detection and the discrimination of the genome of HSV1 and HSV2 in whole blood, blood plasma, cerebrospinal fluid (CSF), bronchoalveolar lavage (BAL) samples, anogenital swabs, mucocutaneous swabs, and throat swabs. Combined with other biological investigation methods (medical imaging, biochemical and immunological analysis, etc.), the results obtained with the HSV1 HSV2 R-GENE® kit are an aid to the diagnosis of HSV1 and HSV2 viruses in patients showing pathological condition suggesting an herpesviridae infection. This kit is intended for in vitro diagnostic use only, in clinical laboratories by laboratory health professionals. Limitation of the test: This kit cannot be used for screening donors.	C

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HSV1 & 2 VZV R-GENE®	69-014B	Using the real-time amplification PCR technique after extraction of viral DNA, the HSV1 & 2 VZV R-GENE® kit is designed to: • Detect and/or quantify and differentiate the HSV1 and HSV2 viral genomes in whole blood, blood plasma, cerebrospinal fluid and bronchoalveolar lavage. • Detect and differentiate the HSV1 and HSV2 viral genomes in throat swabs, anogenital swabs and mucocutaneous swabs. • Detect and/or quantify the VZV viral genome in whole blood, blood plasma and cerebrospinal fluid. • Detect the VZV viral genome in mucocutaneous swabs. Combined with other biological investigation methods (medical imaging, biochemical and immunological analysis, etc.), the results obtained with the HSV1&2 VZV R-GENE® kit are an aid to the diagnosis and monitoring of HSV1, HSV2 and VZV virus in patients showing pathological condition suggesting an herpesviridae infection. This kit is intended for in vitro diagnostic use only, in clinical laboratories by laboratory health professionals.	C
VZV R-GENE®	71-022	The VZV R-GENE® kit, using the real-time PCR technology after extraction of the viral DNA, enables the detection of the genome of VZV in whole blood, blood plasma, and cerebrospinal fluid (CSF) samples, and in mucocutaneous swabs. Combined with other biological investigation methods (medical imaging, biochemical and immunological analysis, etc.), the results obtained with the VZV R-GENE® kit are an aid to the diagnosis of VZV virus in patients showing pathological condition suggesting an herpesviridae infection. This kit is intended for in vitro diagnostic use only, in clinical laboratories by laboratory health professionals. Limitation of the test: This kit cannot be used for screening donors.	C
VIDAS® H. pylori IgG	30192	VIDAS® H. pylori IgG (HPY) is an automated qualitative test for use on the instruments of the VIDAS® family, for the detection of anti-Helicobacter pylori IgG antibodies in human serum or plasma (EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS® H. pylori IgG assay is intended as an aid in diagnosis of H. pylori infection in an adult symptomatic population.	C
VIDAS® Anti-HEV IGM	418115	VIDAS® Anti-HEV IgM (HEVM) is an automated qualitative test for use on the VIDAS® family of instruments for the detection of IgM antibody to hepatitis E virus in human serum and plasma, using the ELFA technique (Enzyme Linked Fluorescent Assay). It is intended as an aid in the diagnosis of hepatitis E infection in patients with symptoms and/or clinical signs of hepatitis.	C

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VIDAS® TB-IGRA	423111	The VIDAS® TB-IGRA (TBRA) assay is intended as an aid in the diagnosis of individuals infected with Mycobacterium tuberculosis (latent or active infection). Using human heparinized whole blood, an automated in vitro stimulation with M. tuberculosis associated peptide antigens is performed on the VIDAS® 3 instrument. When stimulated in this manner, M. tuberculosis specific immune T cells can produce IFN-γ (Interferon Gamma). Although the VIDAS® TB-IGRA assay quantitatively detects the IFN-γ, the interpretation of the result for a single patient is strictly qualitative. The VIDAS® TB-IGRA (TBRA) assay is an indirect test for M. tuberculosis infection and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations.	C
VIDAS® DENGUE NS1Ag	423077	VIDAS® DENGUE NS1Ag is an automated qualitative test for use on the VIDAS® family of instruments. It is intended for the detection of dengue NS1 antigen in human serum, using the ELFA technique (Enzyme Linked Fluorescent Assay). It is an aid in the diagnosis of patients with clinical symptoms consistent with dengue infection.	C
VIDAS® IFNg QC Panel	424069	VIDAS® IFNg QC PANEL (IFNg QC) is intended for in vitro diagnostic use in the immunoassay quality control procedure. This material can be used to monitor the reliability and to help minimize the reporting of incorrect test results of the VIDAS® TB-IGRA assay, automated on the VIDAS® 3 instrument. VIDAS® IFNg QC PANEL used in conjunction with the VIDAS® TB-IGRA assay allows the quantitative detection of interferon gamma (IFN-γ).	C
BK Virus R-GENE®	69-013B	The BK Virus R-GENE® kit, using the real-time PCR technology after extraction of the viral DNA, enables to detect and quantify the genome of BK virus in whole blood, plasma, and urine. Combined with other biological investigation methods (medical imaging, biochemical and immunological analysis, etc.), the results obtained with the BK Virus R-GENE® kit are an aid to the diagnosis and monitoring of BK virus infections (primary infections or reactivations) in patients at risk or showing pathological condition suggesting a BK virus infection. This kit is intended for in vitro diagnostic use only, in clinical laboratories by laboratory health professionals. Limitation of the test: This kit cannot be used for screening donors.	C

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Parvovirus B19 R-GENE®	69-019B	The Parvovirus B19 R-GENE® kit, using the real-time PCR technology after extraction of the viral DNA, enables to detect and quantify the genome of Parvovirus B19 in whole blood, plasma and bone marrow. Combined with other biological investigation methods (medical imaging, biochemical and immunological analysis, etc.), the results obtained with the Parvovirus B19 R-GENE® kit are an aid to the diagnosis and monitoring of Parvovirus B19. infections (primary infections or reactivations) in patients at risk or showing pathological condition suggesting a Parvovirus B19 infection. This kit is intended for in vitro diagnostic use only, in clinical laboratories by laboratory health professionals. This kit cannot be used for screening donors.	C
CMV R-GENE®	69-003B	The CMV R-GENE® kit, using the real-time PCR technology after extraction of the viral DNA, enables to detect and quantify the genome of CMV in whole blood, plasma, saliva swabs, CSF, BAL, amniotic fluid and urine. Combined with other biological investigation methods (medical imaging, biochemical and immunological analysis, etc.), the results obtained with the CMV R-GENE® kit are an aid to the diagnosis and monitoring of CMV infections (primary infections or reactivations) in patients at risk or showing pathological condition suggesting a CMV infection. This kit is intended for in vitro diagnostic use only, in clinical laboratories by laboratory health professionals. Limitation of the test: this kit cannot be used for screening donors.	C
EBV R-GENE®	69-002B	The EBV R-GENE® kit, using the real-time PCR technology after extraction of the viral DNA, enables to detect and quantify the genome of Epstein-Barr virus (EBV) in whole blood, plasma, cerebrospinal fluid, and bronchoalveolar lavage. Combined with other biological investigation methods (medical imaging, biochemical and immunological analysis, etc.) the results obtained with the EBV R-GENE® kit are an aid to the diagnosis and monitoring of EBV infections (primary infections or reactivations) in patients at risk or showing pathological condition suggesting a EBV infection. This kit is intended for laboratory healthcare professionals for in vitro diagnosis use only. Limitation of the test: This kit cannot be used for screening donors.	C

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On behalf of the President
Béatrice LYS
Technical Director

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
TTV R-GENE®	423414	The TTV R-GENE® kit, using the real-time PCR technology after extraction of the viral DNA, enables to detect and quantify the genome of TTV in whole blood, plasma and serum samples. Combined with other biological investigation methods (medical imaging, white blood cell count, lymphocyte phenotyping, etc.), the results obtained with the TTV R-GENE® kit allow the monitoring of TTV viral load and are an aid to assess immune function: TTV viral load monitoring can be used to evaluate the immune status of adult transplant patients (Hematopoietic Stem Cell Transplantation, or HSCT, and Solid Organ Transplantation, or SOT). Serum specimen type has been validated on SOT population only. This kit is intended for in vitro diagnostic use only, in clinical laboratories by laboratory health professionals. Limitation of the test: This kit cannot be used for screening donors.	C
VIDAS® Anti-CHIKUNGUNYA IgM	423229 423229-30	VIDAS® Anti-CHIKUNGUNYA IgM is an automated qualitative test for use on the VIDAS® family of instruments, for the detection of IgM antibodies specific to the chikungunya virus in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). It is intended to be used as an aid in the diagnosis of patients with clinical symptoms consistent with chikungunya virus infection	B
VIDAS® Anti-CHIKUNGUNYA IgG	423230 423230-30	VIDAS® Anti-CHIKUNGUNYA IgG is an automated qualitative test for use on the VIDAS® family of instruments, for the detection of IgG antibodies specific to the chikungunya virus in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). It is intended to be used as an aid in the diagnosis of patients with clinical symptoms consistent with chikungunya virus infection.	B
ADENOVIRUS R-GENE®	69-010B	The ADENOVIRUS R-GENE® kit, using the real-time PCR technology after extraction of the viral DNA, enables the detection and quantification of the adenovirus genome in whole blood, plasma, bronchoalveolar lavage fluid (BAL), and stool samples. Combined with other biological investigation methods (medical imaging, biochemical and immunological analysis, etc.), the results obtained with the ADENOVIRUS R-GENE® kit are an aid to the diagnosis and monitoring of adenovirus infections in patients at risk or showing pathological condition suggesting an adenovirus infection. This kit is intended for in vitro diagnostic use only, in clinical laboratories by laboratory health professionals. Limitation of the test: This kit cannot be used for screening donors	C

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ENTEROVIRUS R-GENE®	69-005B	The ENTEROVIRUS R-GENE® kit using the real-time PCR technology after extraction of the viral RNA enables to detect the enterovirus genome in cerebrospinal fluid (CSF), throat swabs, and stool. Combined with other biological investigation methods, the results obtained with the ENTEROVIRUS R-GENE® kit are an aid to the diagnosis of enterovirus infections in patients showing pathological conditions suggesting an enterovirus infection. This kit is intended for in vitro diagnostic use only, in clinical laboratories by laboratory health professionals.	C
Parechovirus R-GENE®	71-020	The Parechovirus R-GENE® kit, using the real-time PCR technology after extraction of the viral RNA, enables to detect the genome of Human Parechovirus (HPeV) in cerebrospinal fluid. Combined with other biological investigation methods, the results obtained with the Parechovirus R-GENE® kit are an aid to the diagnosis of HPeV infections in patients showing pathological condition suggesting a HPeV infection. This kit is intended for in vitro diagnostic use only, in clinical laboratories by laboratory health professionals.	C
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.	B
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.	B

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VIDAS® Varicella-Zoster IgG	30217	VIDAS® Varicella-Zoster IgG (VZG) is an automated qualitative test for use on the instruments of the VIDAS® family, for the detection of IgG antibodies to varicella zoster virus in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). VIDAS® VZG is intended as an aid in the determination of immune status in general population, including pregnant women.	C

*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*
N° 38815 rev. 0	06/04/2022 *04/06/2022*	Création / *Creation*
N° 38815 rev. 1	13/06/2022 *06/13/2022*	Ajout de références / *Addition of references* • EBV R-GENE® - Ref. 69-002B • TTV R-GENE® - Ref. 423414
N° 38815 rev. 2	19/09/2022 *09/19/2022*	Ajout de références / *Addition of references* • VIDAS Anti-CHIKUNGUNYA IgM - Ref. 423229 - 423229-30 • VIDAS Anti-CHIKUNGUNYA IgG - Ref. 423230 - 423230-30
N° 38815 rev. 3	17/03/2023 *03/17/2023*	Modification de l'adresse du site de Combourg *Change of address of the Combourg site*
N° 38815 rev. 4	22/06/2023 *06/22/2023*	Ajout de références / *Addition of references* • ADENOVIRUS R-GENE -Ref. 69-010B • ENTEROVIRUS R-GENE – Ref. 69-005B
N° 38815 rev. 5	13/09/2023 *09/13/2023*	Ajout de référence / *Addition of reference* • Parechovirus R-GENE – Ref. 71-020

Signé par :
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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
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N° 38815 rev. 6	14/05/2024 *05/14/2024*	Ajout de référence / *Addition of reference* • VIDAS® IFNg QC Panel – Ref. 424069
N° 38815 rev. 7	19/06/2025 *06/19/2025*	Mise à jour destination de dispositif/ *update of intended purpose of device* Nouvelle référence du rapport dans le cadre du maintien de la certification *New file reference in the framework of the maintenance of the certification*
N° 38815 rev. 8	28/08/2025 *08/25/2025*	Ajout de références / *Addition of references* • COVID-19 R-GENE® (ref. 424017) • SARS-COV-2/FLUA/FLUB/RSV R-GENE® (ref.424433)
N° 38815 rev. 9	01/09/2025 *09/01/2025*	Mise à jour de la liste des dispositifs médicaux *Update to the list of medical devices*
N° 38815 rev. 10	30/01/2026 *01/30/2026*	Ajout de référence / *Addition of reference* VIDAS® Varicella-Zoster IgG – Ref. 30217

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 / *Not 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 / *Not applicable*

Signé par :
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