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° 38814 rev. 4

Délivré le/*Issued on:* May 6th, 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 - P604696, 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 - P604696, 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 le dépistage prénatal chez les femmes pour déterminer leur état immunitaire vis-à-vis des agents transmissibles.

In vitro diagnostic medical devices: kits, reagents and control materials intended to be used for pre-natal screening of women in order to determine their immune status towards 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:* May 6th, 2025 (included)

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

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Béatrice LYS
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On behalf of the President
Béatrice LYS
Technical Director

GMED - 38814 rev. 4
Modifie le certificat 38814-3

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. - Avenue des Bergeries - 01150 SAINT VULBAS - 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® TOXO IgM	30202	VIDAS® TOXO IgM is an automated qualitative test for use on the VIDAS® family instruments, for the detection of anti-toxoplasma IgM in serum using the ELFA technique (Enzyme Linked Fluorescent Assay).	C
VIDAS® CMV IgG	30204	VIDAS® CMV IgG is an automated quantitative enzyme immunoassay for use on the VIDAS® family instruments for the quantitative measurement, of anti-cytomegalovirus IgG (CMVG) in human serum, using the technique ELFA (Enzyme Linked Fluorescent Assay).	C
VIDAS® TOXO IgG II	30210	VIDAS® TOXO IgG II is an automated quantitative test for use on the VIDAS® family instruments for the quantitative measurement of anti-toxoplasma IgG in human serum or plasma (lithium heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay).	C
VIDAS® RUB IgM	30214	VIDAS® RUB IgM is a qualitative automated enzyme immunoassay for use on the VIDAS® family instruments, for the detection of anti-rubella IgM (RBM) in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay).	C
VIDAS® RUB IgG II	30221	VIDAS® RUB IgG II (RBG) is an automated quantitative test for use on the VIDAS® family instruments, for the quantitative measurement of immunoglobulins G (IgG) directed against the Rubella virus in human serum or plasma (heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay).	C

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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® TOXO IgG AVIDITY	30222	VIDAS® TOXO IgG AVIDITY is an automated qualitative test for use on the VIDAS® family instruments, for the determination of anti-toxoplasma IgG avidity in human serum or plasma (lithium heparin, EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay).	C
VIDAS® CMV IgG Avidity II	413557	VIDAS® CMV IgG Avidity II is an automated qualitative test for use on the VIDAS® family of instruments for the determination of anti-CMV IgG avidity in human serum, using the ELFA technique (Enzyme Linked Fluorescent Assay). This test is an aid in diagnosing CMV infections. VIDAS® CMV IgG Avidity II is intended to be used with the VIDAS® CMV IgG assay (Ref. 30204).	C
VIDAS® TOXO Competition	30211	VIDAS® TOXO Competition is an automated qualitative test for use on the VIDAS® family instruments for the enzyme immunoassay detection of anti-Toxoplasma gondii total Ig in human serum or plasma (lithium heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay).	C
VIDAS® TOXO IGM (TXMN)	424641	VIDAS® TOXO lgM (TXMN) is an automated qualitative assay for use on the VIDAS® family of instruments, for the detection of anti-Toxoplasma gondii lgM in human serum using the ELFA (Enzyme Linked Fluorescent Assay) technique. It is intended to be used for the screening of Toxoplasma gondii infections in pregnant women, as an aid in the diagnosis of acute or recent Toxoplasma gondii infections in general immunocompetent population (adults or children over 1 year old) and in pregnant women, as well as an aid in the diagnosis of congenital toxoplasmosis in neonates, and in children (between 1 and 12 months) born to a mother who contracted toxoplasmosis during pregnancy.	C
VIDAS® CMV IGM (CMVM)	30205	VIDAS® CMV IgM is an automated qualitative enzyme immunoassay for use on the VIDAS® family instruments, for the detection of anti-cytomegalovirus IgM (CMVM) in human serum, using the ELFA technique (Enzyme Linked Fluorescent Assay). It is intended to be used as an aid in diagnosis in patients suspected of CMV acute or recent infections in adult population	C

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

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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*
38814 rev. 0	06/04/2022 *04/06/2022*	NA : création / *NA: creation*
38814 rev. 1	13/06/2022 *06/13/2022*	Ajout de référence / *Addition of reference* VIDAS® TOXO IgM – Ref. 30202-30
38814 rev. 2	15/12/2022 *12/15/2022*	Ajout de référence / *Addition of reference* VIDAS® TOXO Competition – Ref. 30211
38814 rev. 3	14/02/2023 *02/14/2023*	Retrait de référence / *Reference withdrawal* VIDAS® TOXO IgM – Ref. 30202-30
38814 rev. 4	06/05/2025 *05/06/2025*	Ajout de références / *Addition of references* VIDAS® TOXO IGM (TXMN) – Ref. 424641 VIDAS® CMV IGM (CMVM) – Ref. 30205

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*

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