

**Certificat/Certificate:** N° 38814 rev. 1

**Délivré le /Issued on:** June 13th, 2022

**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 - 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 contained in the quality management system audit report(s) 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 : trousse, 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 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:** June 13th, 2022 (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.*

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*Beatrice Lys*  
GMED  
GROUPE LNE  
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**On behalf of the President**  
**Béatrice LYS**  
**Technical 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

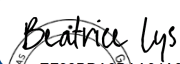

**2. Identification des sites / Identification of sites:**

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

BIOMERIEUX S.A. - Avenue des Bergeries - 01150 SAINT VULBAS - 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 <i>IVD MD Class</i>
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® Toxo IgM	30202-30	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

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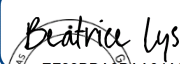

**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**

Nom commercial <i>Commercial name</i>	Références commerciales <i>Commercial references</i>	Destination <i>Intended use</i>	Classe du DM DIV <i>IVD MD Class</i>
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
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

**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>
N° 38814 rev. 0	06/04/2022 04/06/2022	Ajout de référence <i>Addition of reference</i> VIDAS® Toxo IgM - 30202-30

- 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 / *Not 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 / *Not applicable*

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**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**