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° 38820 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 - P604656 - P604657 - P604658 - P604660 - P604664, 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 - P604656 - P604657 - P604658 - P604660 - P604664, 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 d'essai, réactifs, matériaux de contrôle) destinés à être utilisés pour définir, mesurer ou surveiller l'état physiologique et les mesures thérapeutiques, y compris les tests de fertilité et de grossesse.

In vitro diagnostic medical devices (test kits, reagents, control materials) intended to be used for defining, measuring or monitoring physiological status and therapeutic measures including fertility and pregnancy tests.

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.

DocuSigned by:
Beatrice 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

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 *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
VIDAS® Progesterone	30409	VIDAS® Progesterone is an automated quantitative test for use on the VIDAS® family instruments for the quantitative measurement of progesterone in human serum or plasma (lithium heparin or EDTA), using the ELFA technique (Enzyme Linked Fluorescent Assay).	B
VIDAS® Prolactin	30410	VIDAS® Prolactin is an automated quantitative test for use on the VIDAS family instruments, for the enzyme immunoassay determination of human prolactin in human serum or plasma (lithium heparin) using the ELFA technique (Enzyme Linked Fluorescent Assay).	B
VIDAS® Estradiol II	30431	VIDAS® Estradiol II is an automated quantitative test for use on the VIDAS family of instruments for the quantitative measurement of total 17 ß-estradiol in human serum or plasma (lithium heparin), using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS® E2 II assay is intended for use as an aid in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.	B
VIDAS® Testosterone II	414320	VIDAS® Testosterone II is an automated quantitative test for use on the instruments of the VIDAS® family for the quantitative determination of total testosterone in human serum or plasma, using the ELFA technique (Enzyme Linked Fluorescent Assay). It is an aid in the diagnosis and monitoring of disease states that cause excess or deficiency of this androgen.	B
VIDAS® AMH	417011	VIDAS® AMH (AMH) is an automated test for use on the VIDAS® family of instruments, for the quantitative measurement of circulating anti-Müllerian Hormone (AMH) in human serum or plasma (lithium heparin) using the ELFA (Enzyme Linked Fluorescent Assay) technique. The VIDAS® AMH assay is intended to help assess the ovarian follicle reserve in women and young girls over 12 years of age in the context of ovarian dysfunction or controlled or assisted procreation.	B

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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
VIDAS® LH	30406	VIDAS® LH is an automated quantitative test for use on the VIDAS® family instruments for the determination of human luteinizing hormone in human serum or plasma (lithium heparin), using the ELFA technique (Enzyme Linked Fluorescent Assay).	B
VIDAS® FSH	30407	VIDAS® FSH is an automated quantitative test for use on the VIDAS® family instruments for the determination of human follicle stimulating hormone in human serum or plasma (lithium heparin), using the ELFA technique (Enzyme Linked Fluorescent Assay).	B
VIDAS® Ferritin	30411	VIDAS® Ferritin is an automated quantitative test for use on the VIDAS family instruments for the determination of human Ferritin in human serum or plasma (lithium heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay).	B
VIDAS® D-Dimer Exclusion II™	30455	VIDAS® D-Dimer Exclusion II™ is an automated quantitative test for use on the instruments of the VIDAS family for the immunoenzymatic determination of fibrin degradation products (FbDP) in human plasma (sodium citrate) using the ELFA technique (Enzyme Linked Fluorescent Assay). VIDAS D-Dimer Exclusion II is indicated for use in conjunction with a clinical pretest probability assessment model to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE) disease in outpatients suspected of DVT or PE.	C
VIDAS® D-Dimer Exclusion II™	30455-30	VIDAS® D-Dimer Exclusion II™ is an automated quantitative test for use on the instruments of the VIDAS® family for the immunoenzymatic determination of fibrin degradation products (FbDP) in human plasma (sodium citrate) using the ELFA technique (Enzyme Linked Fluorescent Assay). VIDAS® D-Dimer Exclusion II™ is indicated for use in conjunction with a clinical pretest probability assessment model to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE) disease in outpatients suspected of DVT or PE. VIDAS® D-Dimer Exclusion II™ is indicated for use in the HERDOO2 clinical decision rule (CDR) to assess the risk of recurrence of venous thromboembolism (VTE) in women with a first unprovoked VTE. Risk stratification by this CDR is an aid to guide the duration of oral anticoagulant therapy.	C
VIDAS® D-Dimer Exclusion II™	30455-02	VIDAS® D-Dimer Exclusion II™ is an automated quantitative test for use on the instruments of the VIDAS® family for the immunoenzymatic determination of fibrin degradation products (FbDP) in human plasma (sodium citrate) using the ELFA technique (Enzyme Linked Fluorescent Assay). VIDAS® D-Dimer Exclusion II™ is indicated for use in conjunction with a clinical pretest probability assessment model to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE) disease in outpatients suspected of DVT or PE. VIDAS® D-Dimer Exclusion II™ is indicated for use in the HERDOO2 clinical decision rule (CDR) to assess the risk of recurrence of venous thromboembolism (VTE) in women with a first unprovoked VTE. Risk stratification by this CDR is an aid to guide the duration of oral anticoagulant therapy.	C

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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
VIDAS® B R A H M S PCT™	30450	VIDAS® B·R·A·H·M·S PCT™ is an automated test for use on the VIDAS® family of instruments for the determination of human procalcitonin in human serum or plasma (lithium heparin) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. Used in conjunction with other laboratory findings and clinical assessments, VIDAS® B•R•A•H•M•S PCT™ aids in the risk assessment of critically ill patients on their first day of ICU admission, for progression to severe sepsis and septic shock. Used in conjunction with other laboratory findings and clinical assessments, VIDAS® B·R·A·H·M·S PCT™ also aids in decision making on antibiotic therapy for patients with lower respiratory tract infections (LRTI) (including community acquired pneumonia, exacerbation of chronic obstructive pulmonary disease, acute bronchitis) seen during medical consultations, including at the Emergency Department.	C
VIDAS® B R A H M S PCT™	30450-30	VIDAS® B·R·A·H·M·S PCT™ is an automated test for use on the VIDAS® family of instruments for the determination of human procalcitonin in human serum or plasma (lithium heparin) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. Used in conjunction with other laboratory findings and clinical assessments, VIDAS® B•R•A•H•M•S PCT™ aids in the risk assessment of critically ill patients on their first day of ICU admission, for progression to severe sepsis and septic shock. Used in conjunction with other laboratory findings and clinical assessments, VIDAS® B·R·A·H·M·S PCT™ also aids in decision making on antibiotic therapy for patients with lower respiratory tract infections (LRTI) (including community acquired pneumonia, exacerbation of chronic obstructive pulmonary disease, acute bronchitis) seen during medical consultations, including at the Emergency Department.	C
VIDAS® B R A H M S PCT™	30450-86	VIDAS® B·R·A·H·M·S PCT™ is an automated test for use on the VIDAS® family instruments for the determination of human procalcitonin in human serum or plasma (lithium heparin) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. The VIDAS® B·R·A·H·M·S PCT™ is intended for use in conjunction with other laboratory findings and clinical assessments to aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock.	C

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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*
N° 38820 rev. 0	06/04/2022 *04/06/2022*	Ajout de références / *Addition of references* VIDAS® B·R·A·H·M·S PCT™ - 30450-30 VIDAS® D-Dimer Exclusion II™ - 30455-30

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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