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° 38813 rev. 2

Délivré le/*Issued on:* September 13th, 2023

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 - P604665 - P604670 - P606984, 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 - P604665 - P604670 - P606984, 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 au dépistage, au diagnostic, à la stratification ou à la surveillance du cancer.
Dispositifs médicaux de diagnostic in vitro (trousses d'essai, réactifs, matériaux de contrôle) destinés au dépistage, à la détermination ou à la surveillance des marqueurs physiologiques, y compris les allergies et intolérances et les substances ou composants biologiques.

In vitro diagnostic medical devices (test kits, reagents, control materials) intended to be used in screening, diagnosis, staging or monitoring of cancer.
In vitro diagnostic medical devices (test kits, reagents, control materials) intended to be used for the screening, determination or monitoring of physiological markers including allergies and intolerances and substances or biological components.

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:* September 13th, 2023 (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
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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® Protein C	30115	VIDAS® Protein C is an automated quantitative test for use on the VIDAS family instruments, for the quantitative measurement of protein C in human plasma, using the ELFA technique (Enzyme Linked Fluorescent Assay).	B
VIDAS® FT3	30402	VIDAS® FT3 is an automated quantitative test for use on the VIDAS® family instruments, for the quantitative measurement of free triiodothyronine (FT3) in human serum or plasma (lithium heparin) using the ELFA technique (Enzyme Linked Fluorescent Assay).	B
VIDAS® Total IgE	30419	VIDAS® TOTAL IgE is an automated quantitative test for use on the VIDAS family instruments, for the immunoenzymatic determination of total human IgE in human serum or plasma (lithium heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay).	B
VIDAS® FT4	30459	VIDAS® FT4 (FT4N) is an automated quantitative assay for use on the instruments of the VIDAS® family, for the determination of free thyroxine (FT4) in human serum or plasma (lithium heparin), using the ELFA technique (Enzyme Linked Fluorescent Assay). Measurement of Free Thyroxin is intended for use as an aid in the diagnosis and treatment monitoring of thyroid disorders.	B
VIDAS® Anti-TPO	30461	The VIDAS® Anti-TPO assay is an automated quantitative test for use on the instruments of the VIDAS family for the detection of the IgG class of thyroid peroxidase autoantibodies (anti-TPO) in human serum or plasma using the Enzyme Linked Fluorescent Assay (ELFA) technique. The VIDAS® Anti-TPO assay is intended as an aid in the diagnosis of autoimmune thyroid disease.	B

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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
VIDAS® Anti-Tg	30462	The VIDAS® Anti-Tg assay is an automated quantitative test for use on the instruments of the VIDAS family for the detection of the IgG class of thyroglobulin autoantibodies (anti-Tg) in human serum or plasma using the Enzyme Linked Fluorescent Assay (ELFA) technique. The VIDAS® Anti-Tg assay is intended as an aid in the diagnosis of autoimmune thyroid disease.	B
VIDAS® NEPHROCHECK®	421172 421172-03	VIDAS® NEPHROCHECK® is an automated test for use on the VIDAS® 3 instrument for the immunoenzymatic quantitative determination of TIMP-2 (Tissue Inhibitor of Metalloproteinase-2) and IGFBP-7 (Insulin-like Growth Factor-Binding Protein 7) proteins in human urine using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS® NEPHROCHECK® assay is intended to be used in conjunction with clinical evaluation as an aid in the risk assessment for moderate or severe acute kidney injury (AKI) in acutely ill patients.	B
VIDAS® Cortisol S	30451-30	VIDAS® Cortisol S is an automated quantitative test for use on the VIDAS® family instruments, for the quantitative determination of cortisol in human serum, plasma (lithium heparin or EDTA) or urine using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS® Cortisol S test aids in diagnosing or treating adrenocortical disorders.	C
VIDAS® AFP	30413	VIDAS® AFP is an automated quantitative test for use on the VIDAS family instruments for the quantitative measurement of human alpha feto-protein in serum, plasma (lithium heparin or EDTA) or amniotic fluid, using the ELFA technique (Enzyme Linked Fluorescent Assay).	C
VIDAS® CA 125 II™	30426	VIDAS® CA 125 II™ is an automated quantitative test for use on the VIDAS® family instruments, for the measurement of OC 125 antigenic determinants in human serum or plasma (lithium heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay).	C
VIDAS® CA 15-3®	30429	VIDAS® CA 15-3® is an automated quantitative test for use on the VIDAS® family instruments for the quantitative measurement of CA 15-3 levels in human serum or plasma (lithium heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay).	C
VIDAS® CA 19-9™	30427	VIDAS® CA 19-9™ is an automated quantitative test for use on the VIDAS® family of instruments for the measurement of 1116-NS-19-9 reactive antigenic determinants in human serum or plasma (lithium heparin or EDTA) using the ELFA (Enzyme Linked Fluorescent Assay) technique.	C
VIDAS® CEA (S)	30453	VIDAS® CEA (S) is an automated quantitative test for use on the VIDAS family instruments, for the quantitative measurement of Carcinoembryonic antigen (CEA) in human serum or plasma (lithium heparin) using the ELFA technique (Enzyme Linked Fluorescent Assay).	C

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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
NEPHROCLEAR™ CCL14 Test Kit	500025	The NEPHROCLEAR™ CCL14 Test is an automated immunofluorescence assay for use on the ASTUTE140® Meter for the quantitative measurement of CCL14 (C-C motif chemokine ligand 14) in human urine. The NEPHROCLEAR™ CCL14 Test is intended to be used in conjunction with clinical evaluation in adult patients who are in the hospital for an acute illness or condition and have moderate or severe (Stage 2 or 3) acute kidney injury (AKI) as an aid in the risk assessment for developing persistent severe AKI (Stage 3 AKI lasting ≥ 72 hours) within 48 hours of patient assessment.	B
NEPHROCLEAR™ CCL14 Liquid Control kit	500028	The NEPHROCLEAR™ CCL14 Liquid Control Kit (low and high) is intended for in vitro diagnostic use with the NEPHROCLEAR™ CCL14 Test Kit for quantitative detection of CCL14 to support quality control monitoring on the automated ASTUTE140® Meter.	B
VIDAS® T3	30403	VIDAS® T3 is an automated quantitative test for use on the VIDAS® family instruments for the quantitative measurement of total triiodothyronine (T3) in human serum or plasma (lithium heparin) using the ELFA technique (Enzyme Linked Fluorescent Assay). It is intended to be used as an aid in the diagnosis of hyperthyroidism in adult population.	B
VIDAS® T4	30404	VIDAS® T4 is an automated quantitative assay for use on the VIDAS® family of instruments, for the quantitative measurement of total thyroxyne (T4) in human serum or plasma (lithium heparin) using the ELFA (Enzyme Linked Fluorescent Assay) technique. It is intended to be used as an aid in the diagnosis of thyroid disorders in adult population.	B
VIDAS® TBI (GFAP, UCH-L1)	423615 423615-30	The VIDAS® TBI (GFAP, UCH-L1) test is composed of two automated assays - VIDAS® TBI (GFAP) and VIDAS® TBI (UCH-L1) - to be used on the VIDAS® family of instruments for the quantitative measurement of Glial Fibrillary Acidic Protein (GFAP) and Ubiquitin C-terminal Hydrolase (UCHL1) in human serum using the ELFA (Enzyme Linked Fluorescent Assay) technique. The results of both assays are required to obtain an overall qualitative test interpretation. The overall qualitative VIDAS® TBI (GFAP, UCH-L1) test result is used, in conjunction with clinical information, to aid in the evaluation of patients (18 years of age or older), presenting within 12 hours of suspected mild traumatic brain injury (Glasgow Coma Scale score 13-15), to assist in determining the need for a CT (computed tomography) scan of the head. A negative interpretation of VIDAS® TBI (GFAP, UCH-L1) test is associated with the absence of acute intracranial lesions visualized on a head CT scan.	C
VIDAS® FPSA	30440	VIDAS® FPSA is an automated quantitative test for use on the VIDAS® family instruments, for the quantitative measurement of the free fraction of prostate specific antigen (PSA) in human serum or plasma (lithium heparin or EDTA) using the ELFA (Enzyme Linked Fluorescent Assay) technique.	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*
38813 rev. 0	06/04/2022 *04/06/2022*	Ajout de références / Addition of references - VIDAS® AFP - VIDAS® CA 125 II™ - VIDAS® CA 15-3® - VIDAS® CA 19-9™ - VIDAS® CEA (S) - NEPHROCLEAR™ CCL14 Test Kit - NEPHROCLEAR™ CCL14 Liquid Control kit
38813 rev. 1	20/12/2022 *12/20/2022*	Ajout de références / Addition of references - VIDAS® T3 - 30403 - VIDAS® T4 - 30404 - VIDAS® FPSA - 30440 - VIDAS® TBI (GFAP, UCH-L1) - 423615 – 423615-30

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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