



**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 IVD MD <i>Class</i>
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

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

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

**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>
Non Applicable / <i>Not applicable</i>	Non Applicable / <i>Not applicable</i>	Non Applicable / <i>Not applicable</i>

**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*