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° 38952 rev. 2

Délivré le/*Issued on:* June 27th, 2024

Certificat délivré à/*Certificate issued to:* **PHADIA AB**

Rapsgatan 7P PO. Box 6460

751 37 UPPSALA SWEDEN

SRN: SE-MF-000014170

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) P602838-P604645-P604646, 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 P602838-P604645-P604646, 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 y compris des réactifs, matériaux d'étalonnage, matériaux de contrôle et logiciels, destinés à être utilisés pour la confirmation/détermination des allergies et de l'asthme.

In vitro diagnostic medical devices including reagents, calibrators, control materials and software, intended to be used for the confirmation/determination of allergies and asthma

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:* July 1st, 2024 (included)

Valable jusqu'au /*Expiry date:* April 13th, 2027 (included)

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Béatrice LYS
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On behalf of the President
Béatrice LYS
Technical Director

GMED - 38952 rev. 2
Modifie le certificat 38952-1

1. **Le cas échéant, le nom et l'adresse du mandataire /** *If applicable, the name and address of the authorised representative:* Non Applicable / *Not Applicable*

2. **Identification des sites /** *Identification of sites:* **Phadia AB - Rapsgatan 7P - P.O. Box 6460, 751 37 Uppsala - SWEDEN**

3. **Identification des dispositifs /** *Identification of devices:*

Nom commercial *Commercial name*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
ImmunoCAP Specific IgE	ImmunoCAP Specific IgE is an in vitro test system for the quantitative measurement of allergen specific IgE in human serum or plasma. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used by healthcare professionals in clinical laboratories. ImmunoCAP Specific IgE is to be used with the automated instruments Phadia 200, Phadia 250, Phadia 1000, Phadia 2500 or Phadia 5000.	B
ImmunoCAP Phadiatop	ImmunoCAP Phadiatop is an in vitro qualitative and semiquantitative assay for graded determination of IgE antibodies specific to inhalant allergens in human serum or plasma. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used by healthcare professionals in clinical laboratories. ImmunoCAP Phadiatop is to be used with the automated instruments Phadia 200, Phadia 250, Phadia 1000, Phadia 2500 or Phadia 5000.	B
ImmunoCAP Phadiatop Infant	ImmunoCAP Phadiatop Infant is an in vitro qualitative and semiquantitative assay for graded determination of IgE antibodies, in human serum or plasma, specific to allergens that are relevant in atopy of small children. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used by healthcare professionals in clinical laboratories. ImmunoCAP Phadiatop Infant is to be used with the automated instruments Phadia 200, Phadia 250, Phadia 1000, Phadia 2500 or Phadia 5000.	B
ImmunoCAP Total IgE	ImmunoCAP Total IgE is an in vitro test system for the quantitative measurement of circulating total IgE in human serum or plasma. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used by healthcare professionals in clinical laboratories. ImmunoCAP Total IgE is to be used with the automated instruments Phadia 200, Phadia 250, Phadia 1000, Phadia 2500 or Phadia 5000.	B
ImmunoCAP Total IgE Low Range	ImmunoCAP Total IgE Low Range is an in vitro test system for the quantitative measurement of low concentrations of circulating total IgE in human serum or plasma. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used by healthcare professionals in clinical laboratories. ImmunoCAP Total IgE Low Range is to be used with the automated instruments Phadia 200, Phadia 250, Phadia 1000, Phadia 2500 or Phadia 5000.	B

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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 *Commercial name*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
ImmunoCAP ECP	ImmunoCAP ECP is an immunoassay for the quantitative measurement of Eosinophil Cationic Protein (ECP) in human serum. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of asthma in conjunction with other clinical findings. ImmunoCAP ECP is to be used by healthcare professionals in clinical laboratories with the automated instruments Phadia 200, Phadia 250, Phadia 1000, Phadia 2500 or Phadia 5000.	B
ImmunoCAP Tryptase	ImmunoCAP Tryptase is an immunoassay for the quantitative measurement of tryptase in human serum or plasma. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of systemic mastocytosis and mast cell activation events, in conjunction with other clinical findings. ImmunoCAP Tryptase is to be used by healthcare professionals in clinical laboratories and with the automated instruments Phadia 250 or Phadia 1000.	B
ImmunoCAP Specific IgG4	ImmunoCAP Specific IgG4 is an immunoassay for the quantitative measurement of allergen-specific IgG4 antibodies in human serum or plasma. It is intended for in vitro diagnostic use to assess IgG4-associated immune responses, as an aid to evaluate development of allergic tolerance in conjunction with other clinical findings, and is to be used by healthcare professionals in clinical laboratories. ImmunoCAP Specific IgG4 is to be used with the automated instruments Phadia 200, Phadia 250, Phadia 1000, Phadia 2500 or Phadia 5000.	B
ImmunoCAP Specific IgG	ImmunoCAP Specific IgG is an immunoassay for the quantitative measurement of allergen- and antigen-specific IgG antibodies in human serum or plasma. It is intended for in vitro diagnostic use to assess IgG-associated immune responses, as an aid to evaluate allergic disorders in conjunction with other clinical findings, and is to be used by healthcare professionals in clinical laboratories. ImmunoCAP Specific IgG is to be used with the automated instruments Phadia 200, Phadia 250, Phadia 1000, Phadia 2500 or Phadia 5000.	B
ImmunoCAP ISAC E112i	ImmunoCAP ISAC E112i is an in vitro semi-quantitative assay for the measurement of allergen specific IgE antibodies in human serum or plasma. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings. Determination of the IgE sensitization profile to specific and/or cross-reactive allergen components assists in a more detailed evaluation of the allergic patient. The assay is non-automated and is to be used by healthcare professionals in clinical laboratories.	C
Phadia Xplain	Phadia Xplain is an optional software module in Phadia MIA, which provides text comments for ImmunoCAP ISAC E112i test results. The text comments are generated according to rule-based algorithms, which enable the integration of multiple allergen component results from one ImmunoCAP ISAC E112i assay. It is intended to provide interpretive comments to further explain test results from ImmunoCAP ISAC E112i as an aid in diagnosis of IgE mediated allergic disorders. Phadia Xplain is to be used by laboratory and clinical professionals.	B

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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*
38952 rev. 1 *38952 rev. 1*	**08/03/2024** *03/08/2024*	**Retrait de l'instrument Phadia 100 de la destination des produits ImmunoCAP** *Removal of Phadia 100 instrument from the intended use of the ImmunoCAP assays*

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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