

Certificat/Certificate: N° 39148 rev. 0
Délivré le /Issued on: October 7th, 2022

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 sur le(s) rapport(s) d'audit du système de gestion de la qualité référencé(s) P602838, 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 P602838, 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 pour la confirmation/détermination des allergies et de l'asthme.

In vitro diagnostic medical devices including reagents intended to be used for the confirmation/determination of allergies and asthma.

Voir détails sur addendum / See addendum for additional information

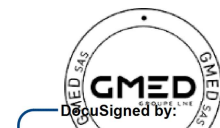
Aux fins de la mise sur le marché de dispositifs de diagnostic in vitro de classe C (près du patient, autodiagnostic ou diagnostic compagnon) et/ou de classe D, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/746 est requis.

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: October 7th, 2022 (included)
Valable jusqu'au /Expiry date: October 6th, 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.



On behalf of the President
Marjorie PERRIMON
Certification Director

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 - Rapskatan 7P - P.O. Box 6460, 751 37 Uppsala - SWEDEN**
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>	Référence aux autres certificats requis pour la mise sur le marché <i>Reference to other certificates required for placing on the market</i>
ImmunoCAP Rapid Wheeze/Rhinitis Child	82-1000-01	ImmunoCAP Rapid Wheeze/Rhinitis Child is an in vitro immunoassay for qualitative determination of allergen specific IgE antibodies in human whole blood. 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 in patients of all ages. ImmunoCAP Rapid is a nearpatient test and is to be used by healthcare professionals.	C	39147 rev.0
ImmunoCAP Rapid Asthma/Rhinitis Adult	82-1001-01	ImmunoCAP Rapid Asthma/Rhinitis Adult is an in vitro immunoassay for qualitative determination of allergen specific IgE antibodies in human whole blood. 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 in patients of all ages. ImmunoCAP Rapid is a nearpatient test and is to be used by healthcare professionals.	B	39147 rev.0



Marjorie PERRIMON
On behalf of the President
Marjorie PERRIMON
Certification 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 / Not Applicable	Non Applicable / Not Applicable	Non Applicable / Not Applicable

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