CERTIFICATE OF REGISTRATION

N° 35147–4

GMED certifies that the quality management system developed by

PHADIA AB

Rapsgatan 7P PO. Box 6460

751 37 UPPSALA SWEDEN

Facility identifier (REPs-generated) : F004186

for the activities

Conception, développement, production et distribution de tests, d'instruments et de logiciels pour le diagnostic in vitro et prestations associées. Détail dans l'ADDENDUM

Design, development, production and distribution of in vitro assays, instruments and software for diagnostic use and services. Detail in ADDENDUM

performed on the location(s) of

PHADIA AB **Rapsgatan 7P, P.O Box 6460 - 751 37 UPPSALA SWE**

has been audited and found to conform to the requirements of the international standard ISO 13485 : 2016 and following regulatory requirements

Australia	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
Canada	Medical Devices Regulations - Part 1 - SOR 98/282
Japan	MHLW MO 169 PMD Act
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D

Début de validité */ Effective date* **December 21st, 2024 (included)**

Valable jusqu'au */ Expiry date :* **December 20th, 2027 (included)**

Etabli le */ Issued on :* **December 13th, 2024**

GMED SAS — DocuSigned by: Béatrice LYS — EF33BDA9...

On behalf of the President

Béatrice LYS

Technical Director

GMED is authorised under the Medical Devices Single Audit Program
This certificate is issued according to the rules of GMED Certification
The validity of this certificate can be verified on www.gmed.fr

Renouvelle le certificat 35147-3

GMED_MDSAP2016-F-V0-07-

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

PHADIA AB
Rapsgatan 7P PO. Box 6460
751 37 UPPSALA
SWEDEN

French version :
Conception et développement, production et distribution de tests pour le diagnostic *in vitro* de l'allergie, l'asthme et les maladies auto-immunes.
Conception et développement, production, distribution, activités de service et installation d'instruments et logiciels utilisés avec les tests de diagnostic *in vitro*.

English version :
Design and development, production and distribution of in vitro allergy, asthma and autoimmunity assays for diagnostic use.
Design and development, production, distribution, servicing and installation of instruments and software to handle in vitro assays for diagnostic use.

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1 site / *1 site*

DocuSigned by:
Béatrice LYS
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director