

GMED certifies that the quality management system developed by

DIAGAST

**251 avenue Eugène Avinée, Eurasanté Parc
59120 LOOS FRANCE**

Facility identifier (REPs-generated) : F000686

for the activities

Conception et développement, production, installation et prestations associées de dispositifs médicaux de diagnostic in vitro en immuno-hématologie et maladies infectieuses.

Design and development, production, installation and servicing of medical devices for in vitro diagnostic in immunohematology and infectious disease.

performed on the location(s) of

VOIR ADDENDUM/ SEE ADDENDUM : 3 sites - 59120 LOOS - FRA

**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 4 Production 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

Début de validité / Effective date June 7th, 2024 (included)

Valable jusqu'au / Expiry date : June 12th, 2027 (included)

Etabli le / Issued on : June 7th, 2024



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 35122-6

DocuSigned by:
Beatrice Lys
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**On behalf of the President
Béatrice LYS
Technical Director**

Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites:

DIAGAST
251 avenue Eugène Avinée
Eurasanté Parc
59120 LOOS
FRANCE

French version :

Conception, développement et production -Ventes, installation et prestations associées

English version:

Design, development and manufacturing - Sales, installation and servicing

DIAGAST
110 avenue Eugène Avinée
Eurasanté Parc
59120 LOOS
FRANCE

French version :

Production

English version:

Manufacturing

DIAGAST
180 avenue Eugène Avinée
Eurasanté Parc
59120 LOOS
FRANCE

French version :

Centre de formation

English version:

Training center

3 sites / 3 sites

DocuSigned by:

Beatrice Lys

EF33BDA9BAA04A3...



On behalf of the President
Béatrice LYS
Technical Director