

GMED certifies that the quality management system developed by

DIAGAST

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

D.U.N.S. identification number : 38-152-7001

for the activities

**La conception et le développement, la fabrication, les ventes de dispositifs de diagnostic in vitro
utilisés dans la détection de groupage et de typage sanguin
(voir addendum)**

*The design and development, manufacture, sales of in-vitro diagnostic medical devices used in the
detection of blood grouping and blood typing
(see addendum)*

performed on the location(s) of

**DIAGAST - 251 avenue Eugène Avinée, Eurasanté Parc - 59120 LOOS - FRA
DIAGAST - 80 rue du Dr Alexandre Yersin, Eurasanté Parc - 59120 LOOS - FRA
DIAGAST - 110 avenue Eugène Avinée, Eurasanté Parc - 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 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
Canada	Medical Devices Regulations - Part 1 - SOR 98/282

Début de validité / Effective date February 28th, 2020 (included)

Valable jusqu'au / Expiry date :December 19th, 2021 (included)

Etabli le / Issued on : February 28th, 2020



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
Modifie le certificat 35122-0



**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, fabrication

English version:

Design, development, manufacturing

DIAGAST
80 rue du Dr Alexandre Yersin
Eurasanté Parc
59120 LOOS
FRANCE

French version :

Ventes

English version:

Sales

DIAGAST
110 avenue Eugène Avinée
Eurasanté Parc
59120 LOOS
FRANCE

French version :

Fabrication

English version:

Manufacturing

3 sites / 3 sites



On behalf of the President
Béatrice LYS
Technical Director