

THERMO FISHER DIAGNOSTICS Ltd
16 Shenley Pavilions, Chalkdell Drive,
Shenley Wood
MILTON KEYNES MK56LB
UK
To the attention of Hanna Kocken

Paris, January 30, 2020

Project Manager: Guillaume BERGER
Tel: + 33 1 40 43 38 05
E-mail : guillaume.berger@lne-gmed.com

Re: Certification of company quality system
Ref.: SRU /GBE / 375/20

Dear Madam,

We are writing to inform you of the results of your application for certification further to the audit carried out on October 17th and November 5th, 2019

Taking account of:

- the examination of the conclusions of the *renewal* audit P600209-1,
- the opinion of the Comité de Lecture,

The decision is as follows:

Renewal of the certificates NF EN ISO 13485:2016 and ISO 9001:2015 with change of address of :

- the Spanish office in Barcelona: *Thermo Fisher Diagnostics SLU - Carretera de l'Hospitalet 147, CityPark, Edificio Londres 3^a Planta – 08940 Cornellà de Llobregat – Spain.*

We are pleased to send you the corresponding certificates No.32629 rev.5, following the international Standards *NF EN ISO 13485:2016* and No.34034 rev.4, following the international Standards *ISO 9001:2015* and wish to remind you that this enables you to use the G-MED mark according to the applicable rules of use of the G-MED mark.

Yours sincerely,

Guillaume BERGER
Certification Project Manager
In vitro Medical Devices Department
GMED

P.O.P. 

Encl.: 2 Certificates quoted above (x5)

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

THERMO FISHER DIAGNOSTICS LIMITED
16 Shenley Pavilions Chalkdell Drive, Shenley Wood,
MILTON KEYNES MK5 6LB UNITED KINGDOM

pour les activités
for the activities

Vente, commercialisation, stockage, distribution et activités d'installation et de formation pour les dispositifs médicaux de diagnostic in vitro et leurs accessoires, incluant les tests, les systèmes, les instruments, les réactifs, les consommables et les pièces de rechange.

Sales, marketing, storage, distribution, installation, servicing and training activities for in vitro diagnostic medical devices and their accessories, including assays, systems, instruments, reagents, consumables and spares.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485 : 2016 - NF EN ISO 13485 : 2016

Début de validité / Effective date January 30th, 2020 (included)

Valable jusqu'au / Expiry date : February 8th, 2023 (included)

Etabli le / Issued on : January 30th, 2020



CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 32629-5

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 32629-4



On behalf of the President
Béatrice LYS
Technical Director

Ce certificat couvre les sites suivants :
This certificate covers the following sites:

THERMO FISHER DIAGNOSTICS LIMITED

- 16 Shenley Pavilions, Chalkdell Drive - Milton Keynes MK5 6LB - UK
- Tudor Road, Manor Park, Runcorn, WA7 1TA. - UK
- Stafford House, Boundary Way - Hemel Hempstead HP2 7GE - UK
- Wade Road - Basingstoke, RG24 8PW - UK
- 25/28 North Wall Quay - Dublin 1 - Republic of Ireland

THERMO FISHER DIAGNOSTICS SAS

- 6 Route de Paisy - 69571 Dardilly - France
- 2 Avenue des Chaumes, Saint Quentin Yvelines Cedex - 78056 Montigny-le-Bretonneux - France
- 2 Rue Louis Armand - 92600 Asniere sur Seine - France

THERMO FISHER DIAGNOSTICS SLU

- Carretera de l'Hospitalet 147, CityPark, Edificio Londres 3ª Planta – 08940 Cornellà de Llobregat – Spain
- Via De Los Poblados, 17 Nave 3-13 - 28033 Madrid – Spain

THERMO FISHER DIAGNOSTICS Sociedade Unipessoal LDA

- Lagoas Pard, Edificio 11, Piso 0 - 2740-270 Porto Salvo - Portugal

THERMO FISHER DIAGNOSTICS NV/SA

- 2, Pontbeekstraate - 1702 Groot-Bijgaarden - Belgium

THERMO FISHER DIAGNOSTICS BV

- Scheepbouwersweg 1B – 1121 PC Landsmeer – Netherlands
- Fultonbaan 24 – 3439 Nieuwegein – Netherlands
- Takkebijsters 1 – 4817 BL Breda – Netherlands

THERMO FISHER DIAGNOSTICS S.P.A

- Rodano, Strada Rivoltana – 20090 Milan – Italy
- Via G.B. Tiepolo 18 – 20900 Monza – Italy

THERMO FISHER DIAGNOSTICS APS

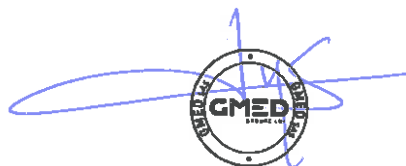
- Gydevang 33 – 3450 Allerød - Denmark
- Kamstrupvej 90 – 4000 Roskilde – Denmark

THERMO FISHER DIAGNOSTICS AB

- Rapskatan 7P, Box 6460 – 75137 Uppsala – Sweden

THERMO FISHER DIAGNOSTICS AS

- Ullernchaussen 52 – 0379 Oslo – Norway



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pour les activités
for the activities

Vente, commercialisation, stockage, distribution et activités d'installation et de formation pour les produits de diagnostic et leurs accessoires, incluant les tests, les systèmes, les instruments, les réactifs, les consommables et les pièces de rechange.

Sales, marketing, storage, distribution, installation, servicing and training activities for diagnostic products and their accessories, including assays, systems, instruments, reagents, consumables and spares.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 9001 : 2015

Début de validité / Effective date January 30th, 2020 (included)

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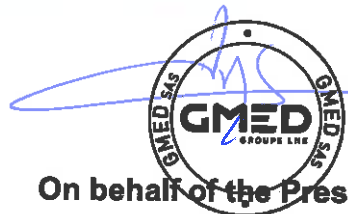


**CERTIFICATION
DE SYSTEMES
DE MANAGEMENT**
Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 34034-4

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 34034-3



On behalf of the President
Béatrice LYS
Technical Director

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