

*GMED certifies that the quality management system developed by*

**Eurobio Scientific GmbH**

**Marie-Curie-Strasse 1**

**53359 Rheinbach GERMANY**

**Facility identifier (REPs-generated) : F008807**

*for the activities*

**Développement, production et distribution de systèmes de biologie moléculaire pour le diagnostic en oncologie et des prédispositions génétiques.**

*Development, production and distribution of molecular biological systems for diagnostics in the field of oncology and genetic predispositions.*

*performed on the location(s) of*

**Eurobio Scientific GmbH - Marie-Curie-Strasse 1 - 53359 Rheinbach - DEU  
Eurobio Scientific - 7 avenue de Scandinavie - ZA de Courtaboeuf - 91940 Les Ulis - 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. 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 March 27th, 2026 (included)**

**Valable jusqu'au / Expiry date : March 26th, 2029 (included)**

**Etabli le / Issued on : March 27th, 2026**



GMED is recognised 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.lne-gmed.com](http://www.lne-gmed.com).



**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:*

French version :

Développement, production et distribution de systèmes de biologie moléculaire pour le diagnostic en oncologie et des prédispositions génétiques.

*English version:*

*Development, production and distribution of molecular biological systems for diagnostics in the field of oncology and genetic predispositions.*

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**Eurobio Scientific GmbH - Marie-Curie-Strasse 1, 53359 Rheinbach, Germany.**

French version :

Siège Social - Conception – Fabrication – Contrôle Final – Distribution

*English version:*

*Headquarters - Design – Manufacture – Final control – Distribution*

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**Eurobio Scientific - 7 avenue de Scandinavie - ZA de Courtaboeuf - 91940 Les Ulis - France**

French version :

Distribution

*English version:*

*Distribution*

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**2 sites / 2 sites**

Signé par :  
  
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**On behalf of the President  
Béatrice LYS  
Technical Director**