

COVER LETTER

Re.: Taiwan Technical Cooperation Programme on Exchange of Medical Device GMP and ISO 13485 Audit Reports

Within the frame of the Technical Cooperation Programme on Exchange of Medical Device Quality Management System Regulation and ISO 13485 Audit Reports between R.O.C. TFDA authorized Medical devices QMS Auditing Organizations and EU Notified Body Partners,

we hereby certify to have delivered conformity certificate to:

BIOMERIEUX S.A.
376 Chemin de l'Orme
69280 MARCY-L'ETOILE FRANCE

Location(s): **See addendum**

Activities scope: **Design, manufacturing, sales and distribution of in vitro diagnostic medical devices, including in molecular biology, and technical aid.**
Sales and distribution of medical devices.

Certificate n°: **GMED - 10282 rev. 16 (Effective date: October 11, 2024 - Expiry date: November 7th, 2027).**

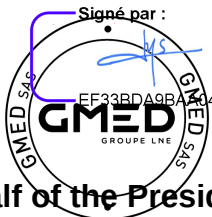
Audit report n°: **P608204_P2 dated June 27th, 2025.**

corresponding to the most recent audit of the quality system according to ISO 13485:2016.

List of TFDA product licenses issued (if applicable): Refer to the attachment "List of TFDA product license issued" of the audit report.

The present cover letter, the QS certificate, the complete audit report and the certificate for Foreign Government need to be sent to Taiwan Department of Health for licensing.

Signé par :

EF33BDA9BA404A3...


On behalf of the President
Béatrice LYS
Technical Director

This certificate covers the following activities and sites:

**BIOMERIEUX S.A.
376, Chemin de l'Orme
69280 MARCY-L'ETOILE
FRANCE**

**Design, manufacturing, sales and distribution of in vitro diagnostic medical devices,
including in molecular biology, and technical aid.
Sales and distribution of medical devices.**

- **376, Chemin de l'Orme - 69280 MARCY-L'ETOILE - FRANCE**
- **3 route de Port Michaud - 38390 LA-BALME-LES-GROTTEs - FRANCE**
- **5 rue des Aqueducs - 69290 CRAPONNE - FRANCE**
- **Avenue des Bergeries - 01150 SAINT-VULBAS - FRANCE**
- **Centre Christophe Mérieux - 5 rue des Berges - 38024 GRENOBLE CEDEX 01 - FRANCE**
- **138 rue Louis Pasteur - Parc Technologique Delta Sud - 09340 VERNIOLLE - FRANCE**
- **4 bis, rue des Coutures - 35270 COMBOURG - FRANCE**

7 sites / 7 facilities

Signé par :

FF33BDA9BBA04A3...


**On behalf of the President
Béatrice LYS
Technical Director**