

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

GMED certifica che il Sistemi di gestione per la qualità sviluppato da

TECHNOGENETICS S.p.A

Piazza Cinque Giornate, 1

20129 Milano ITALY

pour les activités / for the activities / per le attività

Conception, développement, fabrication, ventes, distribution et service après-vente de dispositifs médicaux de diagnostic in vitro, d'analyseurs et de réactifs auxiliaires pour le diagnostic et la gestion des maladies infectieuses, génétiques, endocriniennes et immunologiques.

Design, development, manufacturing, sales, distribution and after-sales servicing of in vitro diagnostic medical devices, analyzers and related ancillary reagents for the diagnosis and management of infectious disease, genetic, endocrine and immunological disorders.

Progettazione, sviluppo, produzione, distribuzione, vendita e supporto post-vendita di dispositivi medici diagnostici in vitro, analizzatori e reagenti accessori per la diagnosi e la gestione di malattie infettive, disordini genetici, endocrini ed immunologici.

réalisées sur le(s) site(s) performed on the location(s) / realizzate da

Voir addendum / See addendum / Vedere addendum

est conforme aux exigences des normes internationales

complies with the requirements of the international standards

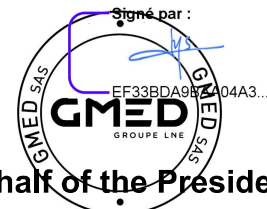
è conforme ai requisiti delle norme internazionali

ISO 13485 : 2016

Début de validité / Effective date / Valido dal : June 2nd, 2026 (included)

Valable jusqu'au / Expiry date / Valido fino al : June 11th, 2029 (included)

Etabli le / Issued on / Rilasciato il : June 2nd, 2026



On behalf of the President
Béatrice LYS
Technical Director



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

GMED N° 33362-7

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

Renouvelle le certificat 33362-6

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

French version :

Conception, développement, fabrication, ventes, distribution et service après-vente de dispositifs médicaux de diagnostic in vitro, d'analyseurs et de réactifs auxiliaires pour le diagnostic et la gestion des maladies infectieuses, génétiques, endocriniennes et immunologiques.

English version:

Design, development, manufacturing, sales, distribution and after-sales servicing of in vitro diagnostic medical devices, analyzers and related ancillary reagents for the diagnosis and management of infectious disease, genetic, endocrine and immunological disorders.

Italian version:

Progettazione, sviluppo, produzione, distribuzione, vendita e supporto post-vendita di dispositivi medici diagnostici in vitro, analizzatori e reagenti accessori per la diagnosi e la gestione di malattie infettive, disordini genetici, endocrini ed immunologici.

TECHNOGENETICS S.p.A
Piazza Cinque Giornate, 1
20129 MILANO
ITALY

French version:
Siège social, responsable de la mise sur le marché
English version:
Headquarter, legal manufacturer

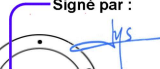
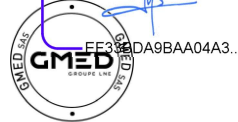
TECHNOGENETICS S.p.A
Via della Filanda 24-26
26900 LODI
ITALY

French version:
Conception, fabrication et contrôle final, ventes, distribution et service après-vente
English version:
Design, manufacturing and final control, sales, distribution and after-sales servicing

TECHNOGENETICS S.p.A
Localita' Area Industriale ASI SNC
83040 Morra de Sanctis (AV)
ITALY

French version:
Conception
English version:
Design

3 sites

Signé par :



On behalf of the President
Béatrice LYS
Technical Director