DECLARATION OF CONFORMITY

The undersigned Technogenetics S.r.l., with legal address at 15 Corso Vittorio Emanuele II, 20122 Milano, and operation sites site at 24-26 Via Della Filanda, 26900 Lodi (LO), Italy, C.F. 06614040159, hereby declares under its own responsibility that, the in vitro diagnostic medical device:

- **nCOVID-19 IgG&IgM POCT (REF. CVRT2500)**

fulfils all the provisions listed in the Medical Device Directive 98/79/EC as amended.
Therefore, Technogenetics assures, under its own responsibility, that:

- "*nCOVID-19 IgG&IgM POCT*" are classified as in vitro diagnostic medical devices, which are not included in Annex II of 98/79/EC IVDD, and subsequent changes, and are not IVDs for performance evaluation;
- the above mentioned in vitro diagnostic medical devices satisfy the essential requirements in the Annex I of the national legislative regulations referring to 98/79/EC In Vitro Diagnostic Medical Device Directive and subsequent changes;
- has followed the Conformity assessment procedure as per Annex III, except paragraph 6, because "*nCOVID-19 IgG&IgM POCT*" are not IVDs for self-testing (according to 98/79/EC IVDD and subsequent changes);
- prepare and keep available to the competent Authorities the technical documentation as specified in Annex III to the aforementioned directive for a period of at least five years from the date of production of the last batch.

Lodi, 08-04-2020

Legal Representative
(Salvatore Cincotti)

Imposta di bollo assolta

Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI
E DEL SERVIZIO FARMACEUTICO
UFFICIO 4 DGDMF DISPOSITIVI MEDICO DIAGNOSTICI IN VITRO

DGFDM/IV/P/I.5.1.e.2/2020/71

VISTA la direttiva 98/79/CE relativa ai dispositivi medico-diagnostici in vitro;
VISTO il D.Lgs. n. 332/2000 recante attuazione della direttiva 98/79/CE;
VISTA l'istanza datata 17/04/2020 presentata dalla ditta Technogenetics S.r.l. con sede legale in Corso Vittorio Emanuele II, 15 - 20122 - Milano, Italia, C.F. 06614040159 P.IVA 09279340153;
CONSIDERATO che la Ditta istante ha effettuato i versamenti richiesti dal D.M. 16 Gennaio 2019;
VISTI gli atti d'ufficio;

HAVING REGARD *to 98/79/EC directive concerning the in vitro diagnostic medical devices;*
HAVING REGARD *to Legislative Decree (D. Lgs.) n. 332/2000 reporting the accomplishment of 98/79/EC directive;*
HAVING REGARD *to the request dated 17/04/2020 submitted by the company Technogenetics S.r.l. with registered place of business in Corso Vittorio Emanuele II, 15 - 20122 - Milano, Italia, C.F. 06614040159 P.IVA 09279340153;*
WHEREAS *this Company paid the fees required by Ministerial Decree (D.M.) January 16, 2019;*
HAVING REGARD *to the official deeds;*

SI ATTESTA

IT IS ATTESTED

che la ditta Technogenetics S.r.l. con sede legale in Corso Vittorio Emanuele II, 15 - 20122 - Milano, Italia, sede di produzione in Via della Filanda 24-26 - 26900 – Lodi, Italia C.F. 06614040159 P.IVA 09279340153 ha marcato CE, come dispositivo medico-diagnostico in vitro, secondo le procedure previste dalla direttiva 98/79/CE, il seguente prodotto:

that the company Technogenetics S.r.l. with registered place of business in Corso Vittorio Emanuele II, 15 - 20122 - Milano, Italia, manufacturing plant in Via della Filanda 24-26 - 26900 – Lodi, Italia C.F. 06614040159 P.IVA 09279340153 affixed CE marking as in vitro diagnostic medical device, according to the Directive 98/79/EC, the following product:

Nome prodotto	Codice Prodotto
nCOVID-19 IgG&IgM POCT	**CVRT2500**

Il suddetto prodotto, in base all'art. 4 della direttiva 98/79/CE, è di libera circolazione e può essere messo in commercio in Italia e in tutto il territorio dell'Unione Europea.
Si rilascia il presente attestato su richiesta dell'interessato per gli usi consentiti dalla legge e per l'esportazione.

The above mentioned product, according to the art. 4 of the 98/79/EC directive, can freely circulate and can be commercialized in Italy and in the whole of the European Union.
This certificate is issued on the interested company's request according to the law and for exporting.

IL DIRETTORE DELL'UFFICIO 4
THE DIRECTOR OF OFFICE 4
(Dott.ssa Antonella Colliardo)

RM/MC

GMED
GROUPE LNE

CERTIFICAT
CERTIFICATE OF REGISTRATION
CERTIFICATO
N° 33362 rev. 2

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by
Il GMED certifica che il Sistemi di gestione per la qualità sviluppato da

TECHNOGENETICS s.r.l.
Corso Vittorio Emanuele II, 15
20122 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, distribution, sales 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) de */ performed on the location(s)* / realizzate da
TECHNOGENETICS s.r.l.
Corso Vittorio Emanuele II, 15, 20122 MILANO - ITA
TECHNOGENETICS s.r.l.
Via della Filanda 24-26, 26900 LODI - ITA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards
é conforme ai requisiti delle norme internazionali

ISO 13485 : 2016

Début de validité */ Effective* / Valido dal : **August 28th, 2019 (included)**
Valable jusqu'au */ Expiry date* / Valido fino al : **December 4th, 2021 (included)**
Etabli le */ Issued on/* Rilasciato il : **August 28th, 2019**

GMED SAS GMED SAS GMED GROUPE LNE

Lionel DREUX
Certification Director

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

GMED_SQ_ITA-F-V0-07-2018

GMED N° 33362–2
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Modifie le certificat 33362-1

GMED
GROUPE LNE

Addendum au certificat n° 33362 rev. 2 page 1/1
Addendum of the certificate n° 33362 rev. 2
Dossier / *File* N° P177412

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

- **TECHNOGENETICS s.r.l. - Corso Vittorio Emanuele II, 15, 20122 MILANO - ITALY:**
  Headquarters

****

- **TECHNOGENETICS s.r.l. - Via della Filanda 24-26, 26900 LODI - ITALY:**
  Design, development, manufacturing, administration facility, distribution, sales and after-sales servicing

****

2 sites / *2 sites*

GMED
Lionel DREUX
Certification Director