

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'Assurance Qualité / Approval full Quality Assurance System

Annexe IV excluant les points 4 et 6 Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro

Annex IV excluding sections 4 & 6 Directive 98/79/EC concerning in vitro diagnostic medical devices

Pour les dispositifs de la liste A IVD, un certificat CE de la conception est requis

For list A IVD devices, a EC design certificate is required

Fabricant / Manufacturer

TECHNOGENETICS S.R.L.

Via Vanvitelli 4

20129 MILANO ITALY

Catégorie du(des) dispositif(s) / Device(s) category

Dispositifs Médicaux de diagnostic in vitro couverts par l'Annexe II Liste B, dans les domaines de la Rubéole, du Cytomégalovirus et de la Toxoplasmose en technologie Chimiluminescence (CLIA).

In vitro diagnostic medical devices covered by Annex II List B, in the field of Rubella, Cytomegalovirus and Toxoplasmosis with CLIA technology.

Voir détails sur addendum

See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P177412, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe IV excluant les points 4 et 6 de la Directive 98/79/CE.

GMED certifies that, on the basis of the results contained in the file referenced P177412, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 98/79/EC, annex IV excluding sections 4 & 6.

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : December 5th, 2018 (included)

Valable jusqu'au / Expiry date : December 4th, 2021 (included)



On behalf of the President
Béatrice LYS
Technical Director

Identification des dispositifs / Identification of devices

Les produits couverts par ce certificat sont référencés sur la liste des produits (1 page) authentifiée par le LNE/G-MED le 28 août 2017.

The products covered by this certificate are listed on the devices's list (1 page) authenticated by LNE/G-MED on August 28th, 2017.

Identification des sites et activités / Identification of locations and activities

- ✚ TECHNOGENETICS s.r.l. - Via Vanvitelli, 4, 20129 Milan – ITALY:**
Headquarters
- ✚ TECHNOGENETICS s.r.l. - Via della Filanda 24-26, 26900 LODI – ITALY:**
Administration facility, design, manufacture and final control

GMED 0459



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



List of IVD List B Annex II to the Directive 98/79/EC

Description of the device / Accessories	Ref commercial CE marked device or item code	Class MD
TGS TA TOXO IgG kit	YB500032	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15050105
TGS TA TOXO IgM kit	YB500033	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15050106
TGS TA TOXO IgG Avidity kit	YB500034	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15050107
TGS TA CMV IgG kit	YB500035	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15040205
TGS TA CMV IgM kit	YB500036	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15040206
TGS TA CMV IgG Avidity kit	YB500037	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15040207
TGS TA Rubella IgG kit	YB500038	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15040105
TGS TA Rubella IgM kit	YB500039	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15040106
TGS TA TOXO Control Set	YB500040	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15500105
TGS TA TOXO Avidity Control Set	YB500041	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15500105
TGS TA CMV Control Set	YB500042	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15500104
TGS TA CMV Avidity Control Set	YB500043	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15500104
TGS TA Rubella Control Set	YB500044	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15500104
TGS TA Rubella IgG Avidity	YB500047	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15040190
TGS TA Rubella Avidity Control Set	YB500048	IVD List B Annex II to the Directive 98/79/EC EDMA CODE 15500104

LNE/G-MED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits

28 AOUT 2017

LNE/G-MED (0459) recognizes that its EC certificate is valid for the medical devices listed