

Ce document complémentaire GMED n° 39015 rev.0 atteste de la validité du certificat CE n° 19347 rev. 20 au regard des informations listées ci-dessous.

This GMED additional document n° 39015 rev.0 attests to the validity of CE certificate n° 19347 rev.20 with regard to the information listed below.

**Fabricant / Manufacturer: Bio-Rad Laboratories Inc.
9500 Jeronimo Road
IRVINE, CA 92618 UNITED STATES**

Identification des dispositifs / Identification of devices

Désignation du dispositif - Accessoires marqués CE / Device designation - CE marked accessories	Référence commerciale ou code article / Commercial reference or article code	Classe du DM / DM Class
Amplichek I	12000527, 12000528, 12000529, 12000530, 12000531	Annex II- List A
Amplichek STI	12000991, 12000992, 12000993, 12000994	Annex II- List B
AmpliClear	00127	Annex II- List B
AmpliProbe CT/GC	00138	Annex II- List B
Liquichek Immunoassay Plus Control	267, 268, 269, 268X	Annex II- List B
Liquichek Immunoassay Plus Control	360, 361, 362, 363, 360X	Annex II- List B
Liquichek Immunoassay Plus Control	12004319, 12004320, 12004321, 12004322	Annex II- List B
Liquichek Immunoassay Premium Control	27110, 27111, 27112, 27113, 27110X	Annex II- List B
Liquichek Maternal Serum Control First Trimester	636, 636X	Annex II- List B

GMED 0459

GMED – 39015 rev.0



Beatrice Lys
On behalf of the President
Béatrice LYS
Technical Director

Medical device name <i>Nom du dispositif médical</i>	Commercial designation <i>Dénomination commerciale</i>	MD Class <i>Classe du DM</i>
Liquichek Maternal Serum II Control	402, 403, 404, 403X	Annex II- List B
Liquichek Pediatric Control	353X, 354, 355	Annex II- List B
Liquichek ToRCH Plus Control, Negative	228, 228X	Annex II- List B
Liquichek ToRCH Plus Control, Positive	227, 227X	Annex II- List B
Liquichek ToRCH Plus Control, Positive Unassayed	239, 239X	Annex II- List B
Liquichek ToRCH Plus IgM Control	229, 229PX, 230, 230NX	Annex II- List B
Liquichek Tumor Marker Control	547, 548, 549, 548X	Annex II- List B
Liquichek Tumor Marker Control	27114, 27115, 27116, 27115X	Annex II- List B
Lyphocheck Assayed Chemistry Control	C-310-5, C-315-5, 313X	Annex II- List B
Lyphocheck Immunoassay Plus Control	370, 371, 372, 373, 370X	Annex II- List B
Lyphocheck Tumor Marker Plus Control	367, 368, 369, 368X	Annex II- List B
Quest Immunoassay/TDM	930	Annex II- List B
VIROCLEAR	00106, 00112	Annex II- List A
VIROCLEAR ToRCH	00118	Annex II- List B
VIROTROL HBc-IgM	00143	Annex II- List A
VIROTROL HBcAg	00144	Annex II- List A
VIROTROL IV	00111	Annex II- List A
VIROTROL ToRCH M	00117A, 00117B	Annex II- List B
VIROTROL PLUS-R	12000538, 12000539	Annex II- List A
VIROTROL HIV-1 gO	00113, 00113X	Annex II- List A
InteliQ Tumor Marker Control	12008289, 12008290, 12008291, 12008292	Annex II- List B
InteliQ Immunoassay Plus Control	12009948, 12009949, 12009950, 12009951	Annex II- List B

GMED 0459

GMED – 39015 rev.0



DocuSigned by:

Beatrice Lys

On behalf of the President
Béatrice LYS
 Technical Director

Sites couverts et Activités / Locations and Activities

Bio-Rad Laboratories Inc.

9500 Jeronimo Road, Irvine, California 92618 -2017 – USA

Conception, fabrication et contrôle final / *Design, manufacturing and final control*

Bio-Rad Laboratories Inc.

9 Holland Drive, Irvine, CA 92618-2506 – USA

Distribution / *Distribution*

Bio-Rad Laboratories Inc.

21 Technology Drive, Irvine, CA 92618 – USA

Fabrication / *Manufacturing*

Bio-Rad Laboratories Inc.

9560 Jeronimo Road, Irvine, CA 92618 – USA

Fabrication / *Manufacturing*

4 sites

GMED	0459
-------------	-------------

GMED – 39015 rev.0



Doc Signed by:

Beatrice Lys

On behalf of the President

Béatrice LYS

Technical Director

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

Bio-Rad Laboratories Inc.
9500 Jeronimo Road
IRVINE, CA 92618 UNITED STATES

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

Matériaux de contrôle

Control materials

Voir document complémentaire GMED / See GMED additional document
n° 39015

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P604435, 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 P604435, 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 : **May 18th, 2022 (included)**

Valable jusqu'au / Expiry date : **May 26th, 2025 (included)**



On behalf of the President
Béatrice LYS
Technical Director