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

Digitally signed by Levința Alexandru
Date: 2023.12.18 11:39:26 EET
Reason: MoldSign Signature
Location: Moldova

GMED GROUPE LNE

DocuSigned by:
Béatrice Lys

GMED 0459

GMED – 39015 rev.0

On behalf of the President
Béatrice LYS
Technical Director

Medical device name *Nom du dispositif médical*	**Commercial designation** *Dénomination commerciale*	**MD Class** *Classe du DM*
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
Lyphochek Assayed Chemistry Control	C-310-5, C-315-5, 313X	Annex II- List B
Lyphochek Immunoassay Plus Control	370, 371, 372, 373, 370X	Annex II- List B
Lyphochek 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 HBeAg	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

GMED 345 GMED SAS

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

DocuSigned by:
Beatrice Lys
On behalf of the President
Béatrice LYS
Technical Director

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 19347 rev. 20**
Délivrée à Paris le 18 mai 2022
Issued in Paris on May 18th, 2022

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 aboved 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)**

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

GMED SAS GMED SAS
GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

GMED_c4-F-new2021-V0-09-

GMED 19347 rev. 20
Renouvelle le certificat 19347-19