

ATTESTATION CE / EC CERTIFICATE

Approbation du Système d'assurance Qualité de la Production / Approval of Production Quality Assurance System

ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices

Pour les dispositifs de classe IIb ou III, un certificat CE de type est requis

For class IIb or III devices, a EC type certificate is required

Fabricant / Manufacturer

MERCK MILLIPORE Ltd
Tullagreen Carrigtwohill
CO. CORK IRELAND

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

Filtres stériles et non stériles à usage médical

Sterile and non sterile filtration devices for medical use

Voir document complémentaire GMED / See GMED additional document

n° 38046

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P600461 - P601180, le système d'assurance qualité - pour la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P600461 - P601180, the quality system - for manufacturing and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex V section 3.


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 : February 25th, 2021 (included)

Valable jusqu'au / Expiry date : May 26th, 2024 (included)

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

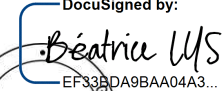
Ce document complémentaire GMED n° 38046 rev. 0 atteste de la validité du certificat CE n° 22433 rev. 6 au regard des informations listées ci-dessous.


This GMED additional document N° 38046 rev. 0 attests to the validity of CE certificate n° 22433 rev. 6 with regard to the information listed below.

Fabricant / Manufacturer: **MERCK MILLIPORE Ltd**
Tullagreen Carrigtwohill
CO. CORK IRELAND

Identification des dispositifs / Identification of devices

Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Référence commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM <i>MD class</i>
Millex®-GS Filter Unit (Non-Sterile)	SLGS02510	Ila
Millex®-OR Filter Unit (Non-Sterile)	SFGL02500	Ila
Millex®-HA Filter Unit (Non-Sterile)	SLHA02510	Ila
Millex®-FG Filter Unit (Non-Sterile)	SLFG0250M	Ila
Dualex™ Transducer Protector (Non-Sterile)	SLTP025BM	Ila
Cathivex®-GV Filter Unit (Sterile)	SLGV0250S	Ila
Dualex™ Plus Transducer Protector (Sterile)	SLGVS25PS	Ila
Dualex™ Ultra Transducer Protector (Sterile)	SLGVS25US	Ila
Dualex™ Transducer Protector (Sterile)	SLGVS25XS	Ila
Millex® Vial Vent (Sterile)	SLGVS25LS	Ila
Millex® Vent With Needle (Sterile)	SLFGN25VS	Ila
Vented Millex®-AA Filter Unit (Sterile)	SLAAV255F	Ila
Millex®-FG Filter Unit (Sterile)	SLFG025LS	Ila

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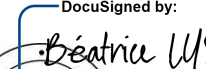
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On behalf of the President
Béatrice LYS
 Technical Director

Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Référence commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM <i>MD class</i>
Vented Millex®-GS Filter Unit (Sterile)	SLGSV255F	Ila
Vented Millex®-GV Filter Unit (Sterile)	SLGVV255F	Ila
Millex®-MP Filter Unit (Sterile)	SLMP025SS	Ila
Millex®-MP Filter Unit (Sterile)	SLMPL25SS	Ila
Millex®-OR Filter Unit (Sterile)	SLGL0250S	Ila
Millex®-SV Filter Unit (Sterile)	SLSV025LS	Ila
Optex™-GS Filter Unit (Sterile)	SPGS0250P	Ila
Optex™-GS Filter Unit (Sterile)	SPGS0255W	Ila
Millex®-GV Filter Unit (Sterile)	SLGV013SL	Ila
Millex®-HV Filter Unit (Sterile)	OEM980903	Ila
Millex®-HV Filter Unit (Sterile)	SLHV013SL	Ila
Millex®-AA Filter Unit (Sterile)	SLAA033SB	Ila
Millex®-AA Filter Unit (Sterile)	SLAA033SS	Ila
Millex®-AA Filter Unit (Sterile)	SLAAM33SS	Ila
Millex®-GS Filter Unit (Sterile)	SLGS033SB	Ila
Millex®-GS Filter Unit (Sterile)	SLGS033SS	Ila
Millex®-GS Filter Unit (Sterile)	SLGSM33SS	Ila
Millex®-HA Filter Unit (Sterile)	SLHA033SB	Ila
Millex®-HA Filter Unit (Sterile)	SLHA033SS	Ila
Millex®-HA Filter Unit (Sterile)	SLHAM33SS	Ila
Millex®-GV Filter Unit (Sterile)	SLGV033RB	Ila
Millex®-GV Filter Unit (Sterile)	SLGV033RS	Ila

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On behalf of the President
Béatrice LYS
 Technical Director

Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Référence commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM <i>MD class</i>
Millex®-GV Filter Unit (Sterile)	SLGV33LEK	Ila
Millex®-GV Filter Unit (Sterile)	SLGVGSK33	Ila
Millex®-GV Filter Unit (Sterile)	SLGVM33RS	Ila
Millex®-HV Filter Unit (Sterile)	SLHV033RB	Ila
Millex®-HV Filter Unit (Sterile)	SLHV033RS	Ila
Millex®-HV Filter Unit (Sterile)	SLHVM33RS	Ila
Millex®-VV Filter Unit (Sterile)	SLVV033RS	Ila
Millex®-VV Filter Unit (Sterile)	SLVVM33RS	Ila
Millex®-GP Filter Unit (Sterile)	SLGP033RB	Ila
Millex®-GP Filter Unit (Sterile)	SLGP033RS	Ila
Millex®-GP Filter Unit (Sterile)	SLGPM33RS	Ila
Millex®-HP Filter Unit (Sterile)	SLHP033RB	Ila
Millex®-HP Filter Unit (Sterile)	SLHP033RS	Ila
Millex®-HP Filter Unit (Sterile)	SLHPM33RS	Ila


Sites couverts et Activités / Locations and Activities

- **MERCK MILLIPORE Ltd. – Tullagreen – Carrigtwohill - Co. Cork - IRELAND**
Siège social – Fabrication et de contrôle final / Headquarters – Manufacturing and final inspection

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Béatrice LYS
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On behalf of the President
Béatrice LYS
Technical Director