



# ISO 13485:2016

Relevant for

**Merck Millipore Ltd.**

**Tullagreen, Carrigtwohill**

**T45 KD29 County Cork, Ireland**

**An affiliate of Merck KGaA, Darmstadt, Germany**

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As a trusted partner of our customers, we deliver quality  
- always.

**GMED certifie que le système de management de la qualité développé par**  
*GMED certifies that the quality management system developed by*

**MERCK MILLIPORE Ltd**  
**Tullagreen Carrigwohill**  
**Co. CORK IRELAND**

**pour les activités**  
*for the activities*

**Conception, fabrication, contrôle et mise sur le marché de filtres stériles et non stériles**  
**à usage médical**

*Design, manufacturing, control and sales of sterile and non sterile filtration devices*  
*for medical use*

**réalisées sur le(s) site(s) de**  
*performed on the location(s) of*

**MERCK MILLIPORE Ltd**  
**Tullagreen Carrigwohill - Co. CORK - IRL**

**est conforme aux exigences des normes internationales**  
*complies with the requirements of the international standards*

**NF EN ISO 13485 : 2016 - ISO 13485 : 2016**

**Début de validité / Effective date : May 5th, 2025 (included)**

**Valable jusqu'au / Expiry date : May 19th, 2028 (included)**

**Etabli le / Issued on : May 5th, 2025**

**cofrac**

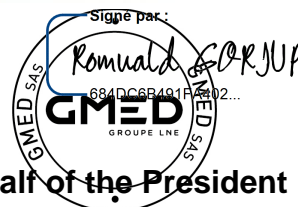


**CERTIFICATION**  
**DE SYSTEMES**  
**DE MANAGEMENT**  
Accréditation n°4-0608  
Liste des sites accrédités  
et portée disponible sur  
[www.cofrac.fr](http://www.cofrac.fr)

GMED N° 22431-8

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

Renouvelle le certificat 22431-7



**On behalf of the President**  
**Romuald GORJUP**  
**Certification Director**

*GMED certifies that the quality management system developed by*

**MERCK MILLIPORE Ltd**

**Tullagreen Carrigtwohill**

**Co. CORK IRELAND**

**Facility identifier (REPs-generated) : F002748**

*for the activities*

**Conception, fabrication et contrôle de filtres stériles et non stériles à usage médical**

*Design, manufacturing and control of sterile and non- sterile filtration devices for medical use*

*performed on the location(s) of*

**MERCK MILLIPORE Ltd - Tullagreen Carrigtwohill - Co. CORK IRL**

**has been audited and found to conform to the requirements of the international standard  
ISO 13485 : 2016 and following regulatory requirements**

Australia	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 Production Quality assurance Procedure
Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
Canada	Medical Devices Regulations - Part 1 - SOR 98/282
Japan	MHLW MO 169 PMD Act
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D 21 CFR 821 (where applicable)

**Début de validité / Effective date May 20th, 2025 (included)**

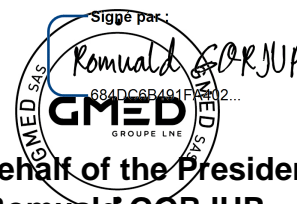
**Valable jusqu'au / Expiry date : May 19th, 2028 (included)**

**Etabli le / Issued on : May 5th, 2025**



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Renouvelle le certificat 35612-2



**On behalf of the President  
Romuald GORJUP  
Certification Director**