Fannin Ltd.
Fannin House, South County Business Park,
Leopardstown, Dublin 18.
Tel: + 353 (01) 2907000
Fax: + 353 (01) 2907118
www.fannin.ie

Fannin Ltd.
I.D.A. Industrial Estate,
Ballybrit Upper, Galway.
Tel: + 353 (01) 2907204
www.lipdiagnostic.com

Customer Notification
Removal of IVD Classification

Date of Notification
12/05/2022

Fannin Ltd., Galway (LIP) wishes to bring to our customers attention the new European In Vitro Medical Devices Regulation (IVDR) (EU) 2017/746 which comes into force on the 26th of May 2022. The IVDR will replace the European In Vitro Diagnostic Medical Device Directive (IVDD) 98/79/EC. A number of Fannin Ltd., Galway (LIP) products are manufactured in line with the IVDD and are registered with the HPRA. This new Regulation brings significant changes to the regulatory requirements for IVD medical devices and introduces a new rule-based classification system with increased requirements and costs to the manufacturing and certification process.

Impact of Change

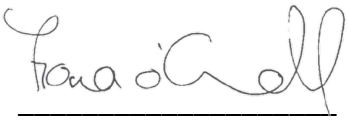
Fannin Ltd., Galway (LIP) have worked diligently over the last two years to protect our product range from any negative impact caused by these changes, however due to these new IVDR requirement, Fannin Ltd., Galway (LIP) must remove the CE IVD marking from the listed products below and the associated documentations. These products will continue to be manufactured as non-IVDs. The removal of the IVD classification may have an impact on your routine use of these products. To limit the impact of this change, we have highlighted alternative products where possible for your review.

Fannin Ltd., Galway (LIP) will continue to manufacture these products with the same high-quality, in compliance to ISO 9001 and our QC testing will remain unchanged under ISO 17025.

Product Code	Product Description	CE IVD product alternatives
W11016	Brazier's CCEY Agar	PB5054A Clostridium Difficile Selective medium
W11185	Listeria Medium (Oxford)	PO0179A Listeria Selective Agar (Oxford)
W11309	Clostridium Difficile Medium	PB5054A Clostridium Difficile Selective medium
W11520	X.L.D. (Harmonised Formula)	W11380 XLD Agar
W11533	CHROMagar E.coli O157 + Cefixime/Tellurite	W11505 CHROMagar STEC
W11070	D.C.L.S.	
W13528	Esculin Broth 5ml	
W14006	Mannitol Selenite Broth 10ml	

Transmission of this Customer Notice
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the devices have been transferred.

I would like to apologise for the inconvenience this may cause. If you have any questions, please contact your local sales representative.



Fiona O'Connell
National Sales Manager
Fannin House, Dublin.
Email: fiona.oconnell@fannin.eu

12/05/2022

Dr Laura Gallagher
QA Manager
Fannin Ltd, Galway.
Email: lipquality@fannin.eu