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Customer Notification
 Discontinuing of culture media products

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 requirements, Fannin Ltd., Galway (LIP) must remove the listed products below from our portfolio from the 26th of May 2022. The discontinuation of the Fannin Ltd., Galway (LIP) products may have an impact on your routine testing. To limit the impact of this change, we have highlighted alternative products where possible for your review.

Product Code	Product Description	Possible CE IVD product alternatives
W11011	Campylobacter Medium (VPT)	PO5091A CCDA Selective Medium
		PB0118A Campylobacter Selective Agar (Skirrow)
W11014	Brucella Blood Agar + Haemin + Vitamin K	W11346 Fastidious Anaerobic Agar + Horse Blood
W11075	G.C. Medium (N.Y.C.)	PB0226A G.C. Selective Agar with Lysed Horse Blood and LCAT
W11214	Dermatophyte Test Medium (DTC-25)	W11232 Dermasel
W11221	Mycobiotic Agar	W11232 Dermasel
W11295	Brilliance Candida Agar	PO5170A Brilliance Candida
W11326	Staph/Strep Selective Agar Modified	W11325 Staph/Strep Agar
W11496	Brilliance MRSA II Agar	PO1210A Brilliance MRSA 2 Agar
W14090	Trichomonas Medium	EB0861C Trichomonas Selective Medium

W11010	Campylobacter Medium (Preston)	
W11077	G.C. Medium (N.Y.C.) (U.C.H.) 4mm	
W11130	D.S.T.	
W11138	D.S.T. Lysed Blood	
W11150	Iso-Sensitest Agar	
W11330	Gardnerella Selective Agar	
W14220	Selenite Cysteine Broth 10ml	
W14235	Motility Nitrate Medium	

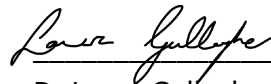
Transmission of this Customer Notice

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.



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 12/05/2022

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