

EU Declaration of Conformity

Product Group	Culture Media (BC, BO, CM, DS, EB, LR, PB, PO, TV) Culture Media for the growth, maintenance and/or processing of microorganisms
Product Code and Product and trade name	See attached product list
Legal Manufacturer	Oxoid Ltd, Wade road, Basingstoke, Hampshire, RG24 8PW, United Kingdom
European Authorized representative	Thermo Fisher Diagnostics B.V. Scheepsbouwersweg 1 B, 1121 PC Landsmeer, The Netherlands
Risk Class	Self-Declared – Non-Annex II Products and Not Self-Test Devices
Conformity route	ANNEX III

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the listed product(s) meet the provisions of EC Directive 98/79/EC concerning in vitro Diagnostic Medical Devices (IVDD).

This declaration is supported by the Quality Management System which is certified to EN ISO 13485:2016 standard (BSI Certificate no. MD 80930).

Signature:

Date: 12th April 2021

Name: James Filer

Function: Vice President, Quality and Regulatory

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Issued in: Basingstoke, Hampshire, UK