

Declaration of Conformity

Oxoid Ltd hereby declare that the products mentioned below are in conformity with the Directive 98/79/EC on *in vitro* diagnostic medical devices and carries the CE mark as evidence of its compliance. This declaration is issued under the sole responsibility of the legal manufacturer, Oxoid Limited.

Product	Please refer to product list in Appendix 1
Legal Manufacturer	Oxoid Ltd Wade Road Basingstoke RG24 8PW United Kingdom
EC Authorised Representative	Thermo Fisher Diagnostics B.V. Scheepsbouwersweg 1B 1121 PC Landsmeer The Netherlands
Products comply with essential requirements of	Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices
Classification	General IVD Non-Annex II Not for Self-testing
Conformity route	Annex III of 98/79/EC
Other applicable standards, directives & regulations	ISO 13485:2016 & EN ISO 13485:2016 EN ISO 14971:2012 A full list of applicable standards, directives and regulations can be found in the technical documentation, which is retained under the control of Oxoid Ltd.
Signed in Dartford, UK (Valid from)	2 nd November 2020
Name & Authority	Nadine Caballero Regulatory Affairs Specialist II, Thermo Fisher Scientific, Microbiology Division
Signature	 .

Appendix 1: Products covered by this Declaration of Conformity

GMDN	Product Code	Product description
51659	DR0100M	DrySpot Staphytest Plus
	DR0850B	Staphytest Plus
	DR0850M	Staphytest Plus