

# 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.

<b>Product</b>	Please refer to product list in Appendix 1
<b>Legal Manufacturer</b>	Oxoid Ltd Wade Road Basingstoke RG24 8PW United Kingdom
<b>EC Authorised Representative</b>	Thermo Fisher Diagnostics B.V. Scheepsbouwersweg 1B 1121 PC Landsmeer The Netherlands
<b>Products comply with essential requirements of</b>	Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices
<b>Classification</b>	General IVD Non-Annex II Not for Self-testing
<b>Conformity route</b>	Annex III of 98/79/EC
<b>Other applicable standards, directives &amp; regulations</b>	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.
<b>Signed in Dartford, UK (Valid from)</b>	2 <sup>nd</sup> November 2020
<b>Name &amp; Authority</b>	Nadine Caballero Regulatory Affairs Specialist II, Thermo Fisher Scientific, Microbiology Division
<b>Signature</b>	 .

**Appendix 1:** Products covered by this Declaration of Conformity

<b>GMDN</b>	<b>Product Code</b>	<b>Product description</b>
51659	DR0100M	DrySpot Staphytest Plus
	DR0850B	Staphytest Plus
	DR0850M	Staphytest Plus