

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
43586	DR0585A	Streptococcal Grouping Kit
43730	DR0586G	Streptococcal Grouping Reagent A
	DR0587G	Streptococcal Grouping Reagent B
	DR0588G	Streptococcal Grouping Reagent C
	DR0589G	Streptococcal Grouping Reagent D
	DR0590G	Streptococcal Grouping Reagent F
	DR0591G	Streptococcal Grouping Reagent G
42632	DR0592G	Polyvalent Positive Control
43730	DR0593G	Extraction Enzyme