ThermoFisher SCIENTIFIC

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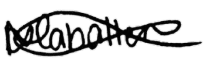
Declaration of Conformity

Remel Europe 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 declarations is issued under the sole responsibility of the legal manufacturer, Remel Europe Limited.

Product	Please refer to product list in Appendix 1
Legal Manufacturer	Remel Europe Limited Remel House Clipper Boulevard West Crossways Dartford Kent DA2 6PT 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 *in vitro* 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 Remel Europe Ltd.
Signed in Dartford, UK (Valid from)	2nd November 2020
Name & Authority	Nadine Caballero Regulatory Affairs Specialist II, Thermo Fisher Scientific, Microbiology Division
Signature	 .

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Appendix 1: Products covered by this Declaration of Conformity

GMDN	Product Code	Product description
50402	R30164501	EDTA Solution
50399	R30858701	Wellcogen Strep B
50399	R30858801	Wellcogen H influenzae b
	R30859001	Wellcogen S pneumoniae
	R30859203	Wellcogen N. meningitidis ACY W135
	R30859502	Wellcogen N. meningitdis B/E.coli K1
	R30859602	Wellcogen Bacterial Antigen Kit