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Non Annex II Products and Not Self Test Devices

REMEL EUROPE LTD.

DECLARATION OF CONFORMITY

Product:

Product Code	Product Description	EDMA Code	GMDN Code
R30163701	Shigella dysenteriae Polyvalent Agglutinating Sera	15 01 90 14	39452
R30163801	Shigella flexneri Polyvalent Agglutinating Sera	15 01 90 14	39452
R30163901	Shigella boydii Polyvalent 1 Agglutinating Sera	15 01 90 14	39452
R30164001	Shigella boydii Polyvalent 2 Agglutinating Sera	15 01 90 14	39452
R30164101	Shigella boydii Polyvalent 3 Agglutinating Sera	15 01 90 14	39452
R30164201	Shigella sonnei Phases 1& 2 Agglutinating Sera	15 01 90 14	39452
R30164301	Alkalescens-Dispar 1-4 Agglutinating Sera	15 01 90 14	39452

Legal Manufacturer's Address:

Remel Europe Ltd.
Remel House,
Clipper Boulevard West
Crossways, Dartford
Kent, DA2 6PT
England.

I, the undersigned, hereby declare that the in-vitro diagnostic medical device(s) described above, bearing the CE marking, conform to the applicable provisions of EC IVD Directive 98/79/EC, as transposed into UK Statutory Instrument 2000 No. 1315, concerning in-vitro diagnostic medical devices.

This declaration is made in accordance with Annex III of the IVD Directive:

Signature: .....

Full Name: Nancy Consterdine
Position: Regulatory Affairs Manager, Europe.

Date: 27 Jan 2012

Supersedes
Declaration Dated: 03 February 2011

Digitally signed by Lazari Cristina
Date: 2023.03.03 11:00:48 EET
Reason: MoldSign Signature
Location: Moldova

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