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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
R30858701	Wellcogen® Strep B Rapid latex agglutination test	15 01 11 01	44029
R30858801	Wellcogen® Haemophilus influenzae b Rapid latex agglutination test	15 01 90 10	17350
R30859001	Wellcogen® Streptococcus pneumoniae Rapid latex agglutination test	14 02 03 02	17392
R30859203	Wellcogen® Neisseria meningitidis A,C,Y,W135 Rapid latex agglutination test	15 01 90 11	17317
R30859502	Wellcogen® Neisseria meningitidis B/E.coli K1 Rapid latex agglutination test	15 01 90 11	17317
R30859602	Wellcogen® Bacterial Antigen Kit Rapid latex agglutination test	15 01 90 90	None
R30164501	Wellcogen EDTA Solution (0.1M)	15 90 90 01	None

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: 23 Jan 2012

Supersedes
Declaration Dated: 03 February 2011

Digitally signed by Lazari Cristina
Date: 2023.05.05 14:33:30 EEST
Reason: MoldSign Signature
Location: Moldova