

Non Annex II Products and Not Self Test Devices

REMEL EUROPE LTD.
DECLARATION OF CONFORMITY

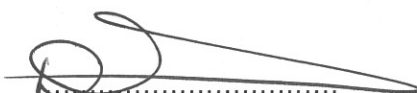
Legal Manufacturer's Address:

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 in the attached sheets, 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

Product Code	Product Description	EDMA Code	GMDN Code
R30858101	Salmonella O Polyvalent (Groups A to G) Agglutinating Sera	15 01 10 03	39521
R30858201	Salmonella O Polyvalent (Groups A to S) Agglutinating Sera	15 01 10 03	39521
R30858501	Salmonella H Polyvalent Phases 1 & 2 Agglutinating Sera	15 01 10 03	39521
R30956701	Salmonella O Factor 2 (Group A) Agglutinating Sera	15 01 10 03	39521
R30956801	Salmonella O Factors 3,10,15,19 (Group E) Agglutinating Sera	15 01 10 03	39521
R30956901	Salmonella O Factor 4 (Group B) Agglutinating Sera	15 01 10 03	39521
R30957001	Salmonella O Factor 5 (Group B) Agglutinating Sera	15 01 10 03	39521
R30957101	Salmonella O Factor 6,7 (Group C1) Agglutinating Sera	15 01 10 03	39521
R30957201	Salmonella O Factor 8 (Group C2) Agglutinating Sera	15 01 10 03	39521
R30957301	Salmonella O Factor 9 (Group D) Agglutinating Sera	15 01 10 03	39521
R30957401	Salmonella Vi Agglutinating Sera	15 01 10 03	39521
R30957501	Salmonella O Factor 10 (Group E1) Agglutinating Sera	15 01 10 03	39521
R30957601	Salmonella O Factor 11 (Group F) Agglutinating Sera	15 01 10 03	39521
R30957701	Salmonella O Factor 13, 22 (Group G) Agglutinating Sera	15 01 10 03	39521
R30957801	Salmonella O Factor 14 (Group H) Agglutinating Sera	15 01 10 03	39521
R30957901	Salmonella O Factor 15 (Group E2) Agglutinating Sera	15 01 10 03	39521
R30958001	Salmonella O Factor 16 (Group I) Agglutinating Sera	15 01 10 03	39521
R30958101	Salmonella O Factor 17 (Group J) Agglutinating Sera	15 01 10 03	39521
R30958201	Salmonella O Factor 18 (Group K) Agglutinating Sera	15 01 10 03	39521
R30958301	Salmonella O Factor 19 (Group E4) Agglutinating Sera	15 01 10 03	39521
R30958401	Salmonella O Factor 20 (Group C2) Agglutinating Sera	15 01 10 03	39521
R30958501	Salmonella O Factor 21 (Group L) Agglutinating Sera	15 01 10 03	39521
R30958601	Salmonella O Factor 27 (Group B) Agglutinating Sera	15 01 10 03	39521
R30958701	Salmonella O Factor 28 (Group M) Agglutinating Sera	15 01 10 03	39521
R30958801	Salmonella O Factor 30 (Group N) Agglutinating Sera	15 01 10 03	39521
R30958901	Salmonella O Factor 35 (Group O) Agglutinating Sera	15 01 10 03	39521
R30959001	Salmonella O Factor 38 (Group P) Agglutinating Sera	15 01 10 03	39521
R30959101	Salmonella O Factor 39 (Group Q) Agglutinating Sera	15 01 10 03	39521
R30959201	Salmonella O Factor 40 (Group R) Agglutinating Sera	15 01 10 03	39521
R30959301	Salmonella O Factor 41 (Group S) Agglutinating Sera	15 01 10 03	39521
R30959801	Salmonella H Rapid Diagnostic 1 Agg Sera	15 01 10 03	39521
R30959901	Salmonella H Rapid Diagnostic 2 Agg Sera	15 01 10 03	39521
R30160101	Salmonella H Rapid Diagnostic 3 Agg Sera	15 01 10 03	39521
R30160201	Salmonella H a Agglutinating Sera	15 01 10 03	39521
R30160301	Salmonella H b Agglutinating Sera	15 01 10 03	39521
R30160401	Salmonella H c Agglutinating Sera	15 01 10 03	39521
R30160501	Salmonella H d Agglutinating Sera	15 01 10 03	39521
R30160601	Salmonella H E Polyvalent Agglutinating Sera	15 01 10 03	39521
R30160701	Salmonella H e,h Agglutinating Sera	15 01 10 03	39521
R30160801	Salmonella H e,n,x Agglutinating Sera	15 01 10 03	39521
R30160901	Salmonella H enz15 Agglutinating Sera	15 01 10 03	39521
R30161001	Salmonella H G Polyvalent Agglutinating Sera	15 01 10 03	39521
R30161101	Salmonella H f,g Agglutinating Sera	15 01 10 03	39521
R30161201	Salmonella H g,m Agglutinating Sera	15 01 10 03	39521
R30161301	Salmonella H g,p Agglutinating Sera	15 01 10 03	39521
R30161401	Salmonella H g,q Agglutinating Sera	15 01 10 03	39521
R30161501	Salmonella H g,s,t Agglutinating Sera	15 01 10 03	39521
R30161601	Salmonella H i Agglutinating Sera	15 01 10 03	39521
R30161701	Salmonella H k Agglutinating Sera	15 01 10 03	39521
R30161801	Salmonella H L Polyvalent Agglutinating Sera	15 01 10 03	39521
R30161901	Salmonella H I,v Agglutinating Sera	15 01 10 03	39521
R30162001	Salmonella H I,w Agglutinating Sera	15 01 10 03	39521
R30162101	Salmonella H m,t Agglutinating Sera	15 01 10 03	39521
R30162201	Salmonella H r Agglutinating Sera	15 01 10 03	39521
R30162301	Salmonella H y Agglutinating Sera	15 01 10 03	39521
R30162401	Salmonella H z Agglutinating Sera	15 01 10 03	39521
R30162501	Salmonella H z4,z23 Agglutinating Sera	15 01 10 03	39521

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Product Code	Product Description	EDMA Code	GMDN Code
R30162601	Salmonella H z6 Agglutinating Sera	15 01 10 03	39521
R30162701	Salmonella H z10 Agglutinating Sera	15 01 10 03	39521
R30162801	Salmonella H z27 Agglutinating Sera	15 01 10 03	39521
R30162901	Salmonella H z29 Agglutinating Sera	15 01 10 03	39521
R30163001	Salmonella H z36 Agglutinating Sera	15 01 10 03	39521
R30163101	Salmonella H z38 Agglutinating Sera	15 01 10 03	39521
R30163201	Salmonella H Polyvalent Phase 2 Agglutinating Sera	15 01 10 03	39521
R30163301	Salmonella H 1,2 Agglutinating Sera	15 01 10 03	39521
R30163401	Salmonella H 1,5 Agglutinating Sera	15 01 10 03	39521
R30163501	Salmonella H 1, 6 Agglutinating Sera	15 01 10 03	39521
R30163601	Salmonella H 1, 7 Agglutinating Sera	15 01 10 03	39521