

*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:  
Position:

Nancy Consterdine  
Regulatory Affairs Manager, Europe.

Date:

27 Jan 2012

Supersedes  
Declaration Dated:

03 February 2011



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[www.remel.com](http://www.remel.com)

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 l,v Agglutinating Sera	15 01 10 03	39521
R30162001	Salmonella H l,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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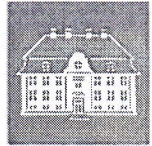
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Product Code	Product Description	EDMA Code	GMDN Code
R30162601	Salmonella H z6 Agglutinating Sera	15 01 10 03	39521
R30162701	Salmonella H z10 Agglutinating Sera	15 01 10 03	39521
R30162801	Salmonella H z27 Agglutinating Sera	15 01 10 03	39521
R30162901	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





1 July 2015

## EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of  
27th of October 1998 on In Vitro Diagnostic Medical Devices

SSI Diagnostica at Statens Serum Institut manufactures and sells the following products:

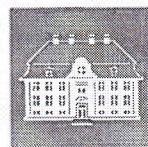
- Antisera for serotyping of *E. coli*
- Antisera for serotyping of pneumococcus
- Antisera for serotyping of *Salmonella*
- Antisera for serotyping of *Streptococcus*
- Antisera for serotyping of *Haemophilus Influenzae*
- Antisera for serotyping of *Shigella*
- Antisera for serotyping of *Yersinia*
- Latex products for serotyping and screening of *E. coli*
- Latex products for serotyping and screening of pneumococcus
- Latex products for serotyping and screening of *Streptococcus*
- Latex products for serotyping and screening of *H. influenzae*
- PCR kit for detection of *E. coli*
- PCR kit for detection of dermatophytes and *Trichophyton rubrum*
- Primermix for PCR detection of virulensgenes in diarrhoeagenic *E. coli* (DEC)
- Antigens isolated from pneumococcus
- Antigen, standard control serum and ELISA kit for detection of *Pseudomonas*
- Antigen *Bordetella Pertussis*
- *Bordetella Pertussis* IgG-PT ELISA kit
- *Legionella* striptest
- *Legionella* antigen detection and pneumococcal antigen detection striptest
- Heat treated glass slides
- Stains and buffers for microbiology
- Buffers for clinical biochemistry
- Mycobacteria isolation media (tubes)
- Broth media
- Tubes and bottled media for yeast and fungi

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STATENS SERUM INSTITUT  
NATIONAL INSTITUTE FOR  
HEALTH DATA AND  
DISEASE CONTROL





- Substrate incorporated media for yeast and fungi
- Prepared media in plates for yeast and fungi
- Minibact N - Detection kit for *Neisseria* identification
- Chromogenic Resistance marker media (Plates)
- Susceptibility test media (plates)
- Substrates incorporated ID media
- Isolation media (plates)
- Media in tubes
- Media in bottles
- SSI Enteric Medium – both dehydrated and ready to use - indicator medium detecting all enterobacteria including *Yersinia* spp.
- Transport media
- SSI Transport Medium (Stuart charcoal swab and pertussis swab for transportation of bacterial samples)

The production is following a quality management system, which is certified by Presafe Denmark A/S certificate number DGM - 645. The products are manufactured according to the following standards and normative documents:

- DS/EN ISO 9001
- DS/EN ISO 13485
- Announcement number 1269 of 12<sup>th</sup> December 2005 by the Danish Ministry of Health regarding the implementation of *Directive 98/79/EC of the European Parliament and of the Council of 27<sup>th</sup> of October 1998 on In Vitro Diagnostic Medical Devices*. The product is not covered by the list A and B in the directive's Annex II.

Statens Serum Institut, 5, Artillerivej, DK-2300 Copenhagen S, Denmark hereby declares that the products are manufactured in accordance with the above listed documents.

01.07.2015

Date

Susanne Sauer  
Quality co-ordinator  
Statens Serum Institut

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