STATENS
SERUM
INSTITUT

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
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HEALTH DATA AND
DISEASE CONTROL

- Substrate incoporated 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.
- Tranport 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 12th 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 27th 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

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