

## 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 A/S manufactures and sells E. coli strains.

The production is following a quality management system, which is certified by Presafe Denmark A/S certificate number DGM - 893. The products are manufactured according to the following standards and normative documents:

- 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 or used for self-testing.

SSI Diagnostica A/S, 2 Herredsvejen, DK-3400 Hillerød, Denmark hereby declares that the product is manufactured in accordance with the above listed documents.

23.04.19

23-04-2019

Sanne Otte

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IVD Production Manager

SSI Diagnostica A/S

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