SSI DIAGNOSTICA

# 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 substrates incorporated ID media. The production is following a quality management system, which is certified by Presafe Denmark A/S certificate number DGM - 893. The product is 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.

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

29/1.2018

Date

Marion Krontoft

Quality co-ordinator

SSI Diagnostica A/S

**SSI Diagnostica A/S**
Herredsvejen 2
3400 Hillerød
Denmark
T +45 4829 9100

ssidiagnostica.com