

## EC DECLARATION OF CONFORMITY

### 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.

SSI Diagnostica manufactures and sells PCR Dermatophyte and C.albicans Real Time PCR kit.

The production is following a Quality Management System, which is certified by the Presafe Denmark A/S – certificate number DGM – 893.

The product is 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.

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

2022-05-20

Date



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