

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 sells ImmuView® *S. pneumoniae* and *L. pneumophila* urinary antigen test. 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 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.

23-10-2018

Date

Charlotte Dan Gradischnig

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Quality co-ordinator

SSI Diagnostica A/S