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 is legal manufacturer of

- ImmuView® *S. pneumoniae* and *L. pneumophila* Urinary Antigen Test (catalogue .no. 95389)
- ImmuView® Reader (catalogue no. 18344)

The Quality Management System 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 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 or used for self-testing.
- IEC 62304
- WEEE and Reach directive

SSI Diagnostica A/S, 2 Herredsvejen, DK-3400 Hillerød, Denmark hereby declares that the products comply with the European Legislation and transpositions into national laws of the member states into which we place the device(s).

02-11-2020

Date

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