EU Declaration of Conformity

Manufacturer:	SSI Diagnostica A/S Herredsvejen 2 DK-3400 Hillerød Denmark
SRN no.	DK-MF-000023922

PRODUCT IDENTIFICATION	
Product Name	**Code / Catalog Number**
ImmuView® *S. pneumoniae* Antigen test	98748
Intended Purpose	**Basic UDI-DI**
The ImmuView® S. pneumoniae Antigen Test is an in vitro rapid lateral flow test, also known as a lateral flow immunochromatographic assay. The assay is intended for qualitative detection of Streptococcus (S.) pneumoniae in urine or cerebrospinal fluid (CSF) specimens from patients with symptoms of pneumonia. The ImmuView® S. pneumoniae Antigen Test can be read visually. The assay is intended to aid in diagnosis of S. pneumoniae. Results from the ImmuView® S. pneumoniae Antigen Test should be interpreted in conjunction with the patient's clinical evaluation and other diagnostic methods.	5713106ImmuView_PutLM

RISK CLASS FOR DEVICES		
Device Classification		**Rule:**
Class:	C	IVDR rule 3 (b)

Common Specifications / Standards

SSI Diagnostica A/S declares that the above-mentioned products meet the provision of the following EU legislation:

- European In Vitro Diagnostic Regulation (2017/746)
- ISO 13485:2019 - Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 14971:2019 – Risk Management
- ISO 13612:2002 – Performance evaluation of in vitro diagnostic medical devices
- ISO 15223-1: 2021 - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
- ISO 18113-1: 2011 - Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
- ISO 18113-2: 2011 - Information supplied by the manufacturer (labelling) - In vitro diagnostic reagents for professional use

COMPANY REPRESENTATIVE:

Place/date: Hilleroed, February 21th 2023

Signature: *Ulla W. Berg*

Title: QA/RA Manager