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 RSV Antigen Test	99110
Intended Purpose	**Basic UDI-DI**
The ImmuView® RSV Antigen Test is a rapid immunochromatographic assay for the qualitative detection of respiratory syncytial virus (RSV) antigen in nasal wash and nasopharyngeal swab specimens from symptomatic patients. This test is intended for in vitro diagnostic use to aid in the diagnosis of respiratory syncytial virus (RSV) infections. The ImmuView® RSV Antigen Test can be read visually	5713106ImmuView_RSVGN

RISK CLASS FOR DEVICES		
Device Classification		**Rule:**
Class:	B	IVDR rule 6

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