SSI DIAGNOSTICA

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 and L . pneumophila* Urinary Antigen Test ImmuView *Reader*	18351 & 95389 18344
Intended Purpose	**Basic UDI-DI**
The ImmuView® S. pneumoniae and L. pneumophila Urinary 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 and Legionella (L.) pneumophila antigens in urine specimens from patients with symptoms of pneumonia. The ImmuView® S. pneumoniae and L. pneumophila Urinary Antigen Test can be read visually or used in conjunction with the ImmuView® reader. The assay is intended to aid in diagnosis of S. pneumoniae and of L. pneumophila serogroup 1 infections. The assay is further intended to aid in the diagnosis of S. pneumoniae infections by detection of S. pneumoniae antigen in cerebrospinal fluid (CSF). Results from the ImmuView® S. pneumoniae and L. pneumophila Urinary Antigen Test should be interpreted in conjunction with the patient's clinical evaluation and other diagnostic methods.	5713106ImmuView_PutLutZH 5713106ImmuView_ReaderRZ

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

Specific for ImmuView Reader

- DS/EN 61010:2010-1 | DS/EN 61010:2010-2-030:2010 | DS/EN 61010-2-101:2022 Safety requirements for electrical equipment for measurement, control, and laboratory use – Particular requirement for in vitro diagnostic (IVD) medical equipment
- IEC 61326 Electrical equipment for measurement, control, and laboratory use – Part 2-6: Particular requirement for in vitro diagnostic (IVD) medical equipment.
- DS/EN 62304:2006 Medical device software – Software life-cycle processes

COMPANY REPRESENTATIVE:

Place/date: Hilleroed, February 21th 2023

Signature: *Ulla W. Berg*

Title: QA/RA Manager