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 *L. pneumophila and L. longbeachae* Urinary Antigen Test	98749
Intended Purpose	**Basic UDI-DI**
The ImmuView® L. pneumophila and L. longbeachae 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 Legionella infections by detection of antigens in urine specimens from patients with symptoms of pneumonia. The ImmuView® L. pneumophila and L. longbeachae Urinary Antigen Test can be read visually. The assay is intended to aid in diagnosis of Legionella (L.) pneumophila serogroup 1 and L. longbeachae infections. Results from the ImmuView® L. pneumophila and L. longbeachae Urinary Antigen Test should be interpreted in conjunction with the patient's clinical evaluation and other diagnostic methods	5713106ImmuView_LutLutXV

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