

## EU Declaration of Conformity

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

PRODUCT IDENTIFICATION	
Product Name	Code / Catalog Number
ImmuView <i>S. pneumoniae</i> and <i>L. pneumophila</i> Urinary Antigen Test	2451 & 10557
Intended Purpose	Basic UDI-DI
<p>The ImmuView® <i>S. pneumoniae</i> and <i>L. pneumophila</i> Urinary Antigen Test is an in vitro rapid lateral flow test, also known as a lateral flow immunochromatographic assay.</p> <p>The assay is intended for qualitative detection of <i>Streptococcus (S.) pneumoniae</i> and <i>Legionella (L.) pneumophila</i> antigens in urine specimens from patients with symptoms of pneumonia.</p> <p>The ImmuView® <i>S. pneumoniae</i> and <i>L. pneumophila</i> Urinary Antigen Test can be read visually or used in conjunction with the ImmuView® reader.</p> <p>The assay is intended to aid in diagnosis of <i>S. pneumoniae</i> and of <i>L. pneumophila</i> serogroup 1 infections.</p> <p>The assay is further intended to aid in the diagnosis of <i>S. pneumoniae</i> infections by detection of <i>S. pneumoniae</i> antigen in cerebrospinal fluid (CSF).</p> <p>Results from the ImmuView® <i>S. pneumoniae</i> and <i>L. pneumophila</i> Urinary Antigen Test should be interpreted in conjunction with the patient's clinical evaluation and other diagnostic methods.</p>	5713106ImmuView_PutLutZH

<b>RISK CLASS FOR DEVICES</b>		
<b>Device Classification</b>		<b>Rule:</b>
<b>Class:</b>	<b>C</b>	IVDR rule 3 (b)
<b>Common Specifications / Standards</b>		
<p>SSI Diagnostica A/S declares that the above-mentioned products meet the provision of the following EU legislation:</p> <ul style="list-style-type: none"> <li>• European In Vitro Diagnostic Regulation (2017/746)</li> <li>• ISO 13485:2019 - Medical devices - Quality management systems - Requirements for regulatory purposes</li> <li>• ISO 14971:2019 – Risk Management</li> <li>• ISO 13612:2002 – Performance evaluation of in vitro diagnostic medical devices</li> <li>• ISO 15223-1: 2021 - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements</li> <li>• ISO 18113-1: 2011 - Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements</li> <li>• ISO 18113-2: 2011 - Information supplied by the manufacturer (labelling) - In vitro diagnostic reagents for professional use</li> </ul>		

**COMPANY REPRESENTATIVE:**

Place/date: February 21<sup>th</sup> 2023

Signature: 

Title: Manager