

## EU Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER			
Name of Company	Address	SRN	
SSI Diagnostica A/S	Herredsvejen 2, DK-3400 Hillerød, Denmark	DK-MF-000023933	
PRODUCT IDENTIFICATION			
Product / Trade Name	Product Code / REF/ Catalog Number	Basic UDI-DI	
ImmuView® Reader	18344	5713106ImmuView_ReaderRZ	
Intended Purpose			
The ImmuView® Reader is an adjunctive instrument for automated reading and interpretation of results for ImmuView® lateral flow immuno-chromatographic in vitro diagnostics test strips.			
IVDR RISK CLASS / COMMON SPECIFICATIONS			
Device Classification		Common Specifications	
Class	A	N/A	
Rule	5(b)		
NOTIFIED BODY			
Name of Company	ID Number	Conformity Assessment Procedure	Certificate Reference(s)
N/A	N/A	In accordance with IVDR, Article 48, 10, SSI Diagnostica A/S shall, as a manufacturer of class A devices, other than devices for performance study, declare the conformity of their products by issuing this EU declaration of conformity referred to in IVDR, Article 17, after drawing up the technical documentation set out in Annexes II and III.	N/A

SSI Diagnostica A/S

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ssid.com

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

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, including the Amendment Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices.

**SSI Diagnostica A/S COMPANY REPRESENTATIVE:**

SIGNATURE:

Name: Pernille Landsbo Elverdal

TITLE: Sr. VP. Clinical Evidence and Medical Affairs, PRRC

PLACE: Hillerød, Denmark

DATE: May 6th, 2026

**SSI Diagnostica A/S**

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