

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 2.0		213414	5713106ImmuView_Read23J8
Intended Purpose			
The ImmuView® Reader 2.0 is an adjunctive instrument for automated reading and interpretation of results for immunochromatographic <i>in vitro</i> diagnostics tests. The instrument is to be used by laboratory professionals/health care professionals only.			
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	N/A

		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.	
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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.

COMPANY REPRESENTATIVE:

SIGNATURE:



Digitally signed by Pernille
L. Elverdal
Date: 2026.01.29 12:27:25
+01'00'

Name: Pernille Landsbo Elverdal

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

PLACE:

Hillerød, Denmark

DATE: January 23, 2026