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**
Pneumococcal CWPS antigen products (CWPS & CWPS Multi)	3459, 68866
Intended Purpose	**Basic UDI-DI**
The SSI Diagnostica pneumococcal CWPS (cell wall polysaccharide) antigen products Pneumoccoccus CWPS and Pneumoccoccus CWPS Multi are intended for binding antibodies recognising epitopes on the pneumococcal cell wall polysaccharide. Pneumoccoccus CWPS and CWPS Multi are intended for preabsorbing human serum samples before quantitation of specific pneumococcal capsular polysaccharide antibodies. Pneumoccoccus CWPS and CWPS Multi may also be used as a coating agent upon performance of an ELISA test. For use by clinical laboratories by their established procedures. The analytical and clinical performance has not been established by manufacturer.	5713106Pneu_CWPS3J

RISK CLASS FOR DEVICES		
Device Classification		**Rule:**
Class:	B	IVDR rule 6

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, October 21th 2022

Title & Signature: QA/RA Manager, *Ulla W. Berg*