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**
ImmuLex Pneumotest kit	51823
Intended Purpose	**Basic UDI-DI**
The SSI Diagnostica ImmuLex™ Pneumotest Kit is intended for visual qualitative serogrouping and serotyping of Streptococcus pneumoniae (pneumococcus) by use of a rapid agglutination test. The ImmuLex™ Pneumotest Kit identifies 92 pneumococcal serotypes using a Chessboard method (see table 1). The Chessboard method provides a quick way to divide the 92 serotypes into Pools, Groups and Types. Furthermore, the Chessboard method identifies and separates the 23 vaccine related serogroups and serotypes from the non-vaccine serogroups and serotypes. The 23 vaccine related serogroups and serotypes that can be detected with the ImmuLex™ Pneumotest Kit are the serogroups 6, 7, 9, 10, 11, 12, 15, 17, 18, 19, 22, 23, 33 and the serotypes 1, 2, 3, 4, 5, 8, 14 and 20 (see table 1). This product is for testing of identified and confirmed, pure cultured isolates and strains of pneumococcus.	5713106Pneu_ImmuL_Kit5L

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*