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 S. pneumoniae OMNI kit	91398
Intended Purpose	**Basic UDI-DI**
The ImmuLex™ S. pneumoniae Omni kit is intended for qualitative detection of the bacterium Streptococcus pneumoniae (S. pneumoniae) directly from a positive blood culture or pure isolates cultured from a blood culture on a plate. The kit will detect capsulated S. pneumoniae belonging to the first 92 serotypes identified. The kit is for in vitro diagnostic use only.	5713106Pneu_ImmuL_OMNI4Y

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

Signature:

Ulla W. Berg

Title: QA/RA Manager