

EU Declaration of Conformity

Manufacturer:	SSI Diagnostica A/S Herredsvejen 2 DK-3400 Hillerød Denmark
SRN no.	DK-MF-000023922

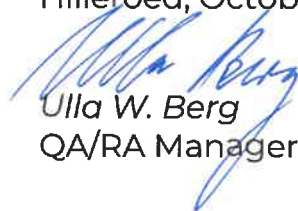
PRODUCT IDENTIFICATION	
Product Name	Code / Catalog Number
Immulex <i>Streptococcus</i> Strep-B kit	54991
Intended Purpose	Basic UDI-DI
SSI Diagnostica ImmuLex™ Strep-B Kit and ImmuLex™ <i>Streptococcus</i> group B antisera are intended for visual qualitative confirmation, serogrouping and serotyping of <i>Streptococcus agalactiae</i> ^{1,2} by use of a rapid agglutination test. It is important to use only pure culture isolates of <i>Streptococcus</i> for determination of bacterial antigens.	5713106Strep_B_ImmuLBK

RISK CLASS FOR DEVICES		
Device Classification		Rule:
Class:	B	IVDR rule 6
Common Specifications / Standards		
<p>SSI Diagnostica A/S declares that the above-mentioned products meet the provision of the following EU legislation:</p> <ul style="list-style-type: none"> • 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