

## EU Declaration of Conformity

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

PRODUCT IDENTIFICATION	
Product Name	Code / Catalog Number
<i>Streptococcus</i> antisera Group B type (Lancefield) Suis type (Neufeld og Lancefield)	Multiple items- eg. 22455, 22280, 44627, 69746
Intended Purpose	Basic UDI-DI
The <i>Streptococcus suis</i> antisera are for visual qualitative identification and bacterial serotyping by means of the Neufeld test <sup>1</sup> (also named the capsular reaction test or the Quellung reaction) or the Lancefield test <sup>2,3</sup> . The <i>Streptococcus</i> group B antisera are intended for visual qualitative identification and bacterial serotyping by means of the Lancefield test <sup>2,3</sup> . It is important to use only pure culture isolates of <i>Streptococcus</i> for determination of bacterial antigens.	5713106Strep_SeraUD

RISK CLASS FOR DEVICES		
Device Classification	Rule:	
<b>Class:</b> 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: <ul style="list-style-type: none"> <li>• European In Vitro Diagnostic Regulation (2017/746)</li> <li>• ISO 13485:2019 - Medical devices - Quality management systems - Requirements for regulatory purposes</li> <li>• ISO 14971:2019 – Risk Management</li> <li>• ISO 13612:2002 – Performance evaluation of in vitro diagnostic medical devices</li> <li>• ISO 15223-1: 2021 - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements</li> <li>• ISO 18113-1: 2011 - Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements</li> <li>• ISO 18113-2: 2011 - Information supplied by the manufacturer (labelling) - In vitro diagnostic reagents for professional use</li> </ul>		

### COMPANY REPRESENTATIVE:

Place/date: Hilleroed, October 21<sup>st</sup> 2022

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

