

## EU Declaration of Conformity

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

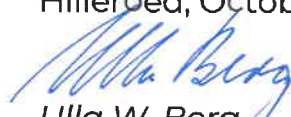
PRODUCT IDENTIFICATION	
<b>Product Name</b>	<b>Code / Catalog Number</b>
<i>E.Coli</i> antisera OK O pool/single, O pool/single, H pool/single	Multiple items- eg. 44292, 44925, 79983, 45740, 45897, 54386, 54397, 85030
<b>Intended Purpose</b>	<b>Basic UDI-DI</b>
<i>Escherichia coli (E. coli)</i> antisera are used as an in vitro diagnostic aid for qualitative manual complete or partial bacterial serotyping by slide agglutination, for overnight agglutination in round bottom microtiter plates and/or agglutination in Widal tubes. It is important to use pure culture isolates for determination of bacterial antigens.	5713106E.Coli_SeraAR

RISK CLASS FOR DEVICES		
<b>Device Classification</b>	<b>Rule:</b>	
<b>Class:</b>	B	IVDR rule 6
<b>Common Specifications / Standards</b>		
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: Hillerød, October 21<sup>th</sup> 2022

Signature:



Ulla W. Berg  
QA/RA Manager

Title: