SSI DIAGNOSTICA

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**
E.Coli antisera OK O pool/single, O pool/single, H pool/single	Multiple items- eg. 44292, 44925, 79983, 45740, 45897, 54386, 54397, 85030
Intended Purpose	**Basic UDI-DI**
Escherichia coli (E. coli) 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		
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