# EU Declaration of Conformity

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

| **PRODUCT IDENTIFICATION** | |
|---|---|
| **Product Name** | **Code / Catalog Number** |
| *Salmonella* antisera | Multiple items- eg. 13301, 13536, 23839, 40250, 50186 |
| **Intended Purpose** | **Basic UDI-DI** |
| *Salmonella* antisera are used as an in vitro diagnostic aid for qualitative manual complete or partial bacterial serotyping by slide agglutination and H phase inversion.<br>It is important to use pure culture isolates for determination of bacterial antigens. | 5713106Salmonella_Sera6K |

| **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