# EU Declaration of Conformity

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|---|---|
| **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** |
| **Selective Culture Media agar plates** | (Several Cat.No according to product catalogue / see homepage www.ssidiagnostica.com) |
| **Intended Purpose** | **Basic UDI-DI** |
| The collection of different general culture media agar plates is to support in vitro diagnostic procedures for general microbiology laboratories. Selective medias augments the growth of the desirable bacteria by inhibiting the growth of undesirable bacteria | 5713106CM_SelectiveS2 |

| **RISK CLASS FOR DEVICES** | | |
|---|---|---|
| **Device Classification** | | **Rule:** |
| **Class:** | A | IVDR rule 5 (a) |

**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
- ISO 23640:2015 - Evaluation of stability of in vitro diagnostic reagents

**COMPANY REPRESENTATIVE:**

Place/date: Hillerød, May 19th 2022

Signature: *Ulla W. Berg*

Title: QA/RA Manager