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**
Culture Media Staining Solutions	(Several Cat.No according to product catalogue / see homepage www.ssidiagnostica.com)
Intended Purpose	**Basic UDI-DI**
Staining solutions are used to support in vitro diagnostic procedures for general microbiology laboratories.	5713106CM_GeneralZL

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