

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
Dermatophyte and <i>C. albicans</i> Real Time PCR kit	99462
Intended Purpose	Basic UDI-DI
The Dermatophyte and <i>C. albicans</i> Real Time PCR Kit is an <i>in vitro</i> diagnostic kit for the quantitative detection of general dermatophytes (pan-dermatophytes), <i>Trichophyton (T.) rubrum</i> and <i>Candida (C.) albicans</i> in nail, skin, and hair specimens.	5713106Derm_RT_PCRVV

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: <ul style="list-style-type: none"> 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: Hillerød, October 21th 2022

Signature:



Ulla W. Berg

Title:

QA/RA Manager