

Technical File – Declaration of Conformity

WI-EU-REG-040 – Annex IV		
Revision: 00	Page 1 of 2	

We

Name + address + Single Registration Number of manufacturer:	Ecolab Deutschland GmbH Ecolab-Allee 1 40789 Monheim am Rhein Germany
Name + address + Single Registration Number of authorized representative:	Not Applicable

declare on our sole responsibility that

the medical device	ANIOSYME SYNERGY WD PLUS
Type / Intended purpose	Detergent/ Cleaning of surgical and medical equipment, medical devices in automatic washing machine and washing tunnel.
Class Rule according to MDR Annex VIII	I Rule 1

Meets all the provisions of the Regulation (EU) 2017/745 on medical devices.

Notified body name, address, ID	Not Applicable
Conformity assessment procedure	Article 52, MDR (Annex II + III)
ID of the certificates issued	Not Applicable
Common Specifications	Not Applicable
Validity	2024-05-26

Valid in conjunction with the batch related release documentation

Missay

1

Monheim, 15 April 2021	Dieter Wirbals Person Responsible for Regulatory Compliance	<i>O</i> ,	Jean-Noël Bertho RD&E Group Leader
Place, date		Place, date	Name and function

Signed on behalf of: [Ecolab Deutschland GmbH]



WI-EU-REG-040 – Annex IV Page 2 of 2 Revision: 00

Medical Device	Brand	Device Subcategory	Part Number / SKU	Basic UDI-DI
ANIOSYME SYN- ERGY WD PLUS	Not Applicable	Detergent	3100860	NA
ANIOSYME SYN- ERGY WD PLUS	Not Applicable	Detergent	3100880	NA
ANIOSYME SYN- ERGY WD PLUS	Not Applicable	Detergent	3100890	NA
ANIOSYME SYN- ERGY WD PLUS	Not Applicable	Detergent	3110180	NA
ANIOSYME SYN- ERGY WD PLUS	Not Applicable	Detergent	3110200	NA
ANIOSYME SYN- ERGY WD PLUS	Not Applicable	Detergent	3110210	NA