

Technical File – Declaration of Conformity

WI-EU-REG-040 – Annex IV

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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 Use	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	26.05.2024	

Valid in conjunction with the batch related release documentation

Monheim, 20 August 2021	Dieter Wirbals	A / I	Sainghin, 20 August 2021	Jean-Noël Bertho
Place, date	Name and function (Person Responsible for Regulatory Compliance)		IDIOCO MOTO	Name and function (RD&E Representative)

Signed on behalf of: [Ecolab Deutschland GmbH]



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Medical Device	Brand	Device Subcategory	Part Number / SKU	Basic UDI-DI
ANIOSYME SYNERGY WD PLUS	Not Applicable	Detergent	3100860	
ANIOSYME SYNERGY WD PLUS	Not Applicable	Detergent	3100880	
ANIOSYME SYNERGY WD PLUS	Not Applicable	Detergent	3100890	
ANIOSYME SYNERGY WD PLUS	Not Applicable	Detergent	3110180	359761LA01C150INQ3
ANIOSYME SYNERGY WD PLUS	Not Applicable	Detergent	3110200	
ANIOSYME SYNERGY WD PLUS	Not Applicable	Detergent	3110210	