

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	Sekusept® MultiEnzyme	
Type / Intended purpose	Cleaner for medical instruments	
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

Milas

Monheim,	Dieter Wirbals	Sainghin,	Jean-Noël Bertho	
15 April 2021	Person Responsible for	15 April 2021	RD&E Group Leader	
·	Regulatory Compliance			
Place, date	Name and function	Place, date	Name and function	

Signed on behalf of: [Ecolab Deutschland GmbH]



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Medical Device	Brand	Device Subcategory	Part Number / SKU	Basic UDI-DI
Sekusept MultiEnzyme	Not Applicable	Cleaner	3046620	NA
Sekusept MultiEnzyme	Not Applicable	Cleaner	3046640	NA