

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 Pure Clean		
Type / Intended Use	Cleaner for manual cleaning of medical instruments and endoscopes		
Class Rule according to MDR Annex VIII	l 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

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Monheim, 20 August 2021	Dieter Wirbals	Sainghin, 20 August 2021	Jean-Noël Bertho
Place, date	Name and function (Person Responsible for Regulatory Compliance)	Place, date	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
Sekusept Pure	Not	Cleaner	3080920	
Clean	Applicable			4028163ED01OI50EXFV
Sekusept Pure	Not	Cleaner	3080940	4020 103ED0 10130EXFV
Clean	Applicable			