

	<b>Technical File – Declaration of Conformity</b>	WI-EU-REG-040 – Annex IV	
		Revision: 01	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


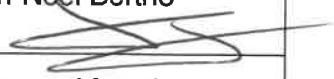
declare on our sole responsibility that

the medical device	<b>Sekumatic® FNZ</b>
Type / Intended Use	Liquid neutralizer for the application in automated re-processors after alkaline cleaning
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 	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: [\[Ecolab Deutschland GmbH\]](#)

Medical Device	Brand	Device Subcategory	Part Number / SKU	Basic UDI-DI
Sekumatic FNZ	Not Applicable	Neutraliser	3023510	4028163ED01OI50INFM
Sekumatic FNZ	Not Applicable	Neutraliser	3023500	
Sekumatic FNZ	Not Applicable	Neutraliser	3040730	
Sekumatic FNZ	Not Applicable	Neutraliser	3026550	