

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	Sekumatic® FNZ
Type / Intended purpose	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	2024-05-26

Valid in conjunction with the batch related release documentation



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

Signed on behalf of: [\[Ecolab Deutschland GmbH\]](#)



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