

## Technical File – Declaration of Conformity

WI-EU-REG-040 – Annex IV

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We

| Name + address + Single Registration<br>Number of manufacturer:              | Ecolab Deutschland GmbH<br>Ecolab-Allee 1<br>40789 Monheim am Rhein<br>Germany |
|--|--|
| Name + address + Single Registration<br>Number of authorized representative: | Not Applicable   |

declare on our sole responsibility that

| the medical device                     | Sekusept Pure Clean   |
|--|---|
| Type / Intended purpose                | Cleaner for manual cleaning of medical instruments and endoscopes |
| Class Rule according to MDR Annex VIII | I<br>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,      | Dieter Wirbals Person Responsible for Regulatory Compliance | Sainghin,     | Jean-Noël Bertho  |
|---------------|---|---------------|-------------------|
| 15 April 2021 |   | 15 April 2021 | RD&E Group Leader |
| 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 Pure Clean | Not Applicable | Cleaner            | 3080920           | NA           |
| Sekusept Pure Clean | Not Applicable | Cleaner            | 3080940           | NA           |