

**Cocune EU Declaration of Conformity**

21064

Version 2.0

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**Version History**

Version	Description of Change
1.0	Initial version
2.0	Update to revise Intended Purpose statement and remove model number prefix

**EU MDR Declaration of Conformity**

**Model Number:** 21-1001, 21-1002, 21-1004, 21-1005

**Basic UDI-DI:** 871846941CCN-123AN2

**Product Name:** Cocune

**Intended Purpose:** to be used for optimal hygiene and infection prevention as a complete body wash

**Manufacturer Name:** Stöpler Medical B.V.

**Manufacturer Address:** Middenwetering 1,  
3543 AR Utrecht,  
The Netherlands

**Manufacturer SRN:** ACT-004.02-20210615-APP000011678

**Notified Body:** NA

**EC Product Certificate:** NA

**EC Quality Certificate:** NA

**Conformity Assessment Procedure:** Annex IV

**Risk Class:** Class I

**Classification Rule:** Rule 1

**Statement:**

We, Stöpler Medical B.V, hereby declare under our sole responsibility that the product specified herein conforms to EU Medical Device Regulation 2017/745.

**Common Specification(s)**

No common specifications were used to demonstrate conformity:

**Signed for and on behalf of:** Stöpler Medical B.V.

**Place:** Utrecht

**Name:** Bart van Liebergen

**Function:** CEO

**Signature:**

**Date:**

DocuSigned by:

*Bart van Liebergen*

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25 AUG. 2021