

## Declaration of Conformity to EU Medical Device Regulation 2017/745

|                                                          |                                                                         |
|----------------------------------------------------------|-------------------------------------------------------------------------|
| <b>Legal Manufacturer</b>                                | Coloplast A/S<br>Holtedam 1, 3050 Humlebaek, DK<br>SRN:                 |
| <b>EU Product Classification according to Annex VIII</b> | IIb<br>Rule Number: 4                                                   |
| <b>Intended Purpose</b>                                  | The product is intended for moist wound healing and exudate management. |
| <b>Basic UDI-DI</b>                                      | 57089322853027E                                                         |
| <b>Conformity Assessment Procedure</b>                   | Annex IX                                                                |
| <b>Notified Body Name and Number</b>                     | DNV Product Assurance AS - (2460)                                       |
| <b>Notified Body Certificate Type and Number</b>         | EU Quality Management System Certificate - 10000376655-PA-NoMA-DNK      |
| <b>Conformity to Common Specification(s)</b>             | No relevant Common Specification to list                                |
| <b>Conformity to other Union Legislation(s)</b>          | No relevant Union Legislation to list                                   |

This EU Declaration of Conformity is applicable for following catalogue numbers:

| <b>Catalogue Number</b>          | <b>Product Name</b> | <b>Original CE Marking Date<br/>yyyy-mm-dd</b> |
|----------------------------------|---------------------|------------------------------------------------|
| 33436 / 334364                   | Biatain Silicone    | 2009-11-06                                     |
| 33404                            | Biatain Silicone    | 2016-09-07                                     |
| 33400                            | Biatain Silicone    | 2016-09-07                                     |
| 33406                            | Biatain Silicone    | 2016-09-07                                     |
| 33434 / 334343 / 334345          | Biatain Silicone    | 2009-11-06                                     |
| 33437 / 334373                   | Biatain Silicone    | 2009-11-06                                     |
| 33408                            | Biatain Silicone    | 2016-09-07                                     |
| 33438 / 334383 / 334384 / 334386 | Biatain Silicone    | 2009-11-06                                     |
| 33400 / 33401                    | Biatain Silicone    | 2016-09-07                                     |
| 33435 / 334353 / 334354          | Biatain Silicone    | 2010-06-14                                     |
| 33405                            | Biatain Silicone    | 2016-09-07                                     |

This EU Declaration of Conformity is issued under the sole responsibility of Coloplast A/S. Coloplast A/S declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled.

Date of signature:

2022-03-31

yyyy-mm-dd

Place of signature:

Humblebaek, Denmark

Place, Country

DKBENB, Benedikte Blom, Head of Regulatory Affairs

Signed on behalf of Coloplast A/S:



Name, Title