



## EC Declaration of Conformity to Council Directive 93/42/EEC and amendments concerning Medical Devices

|                                               |                                                                                                                                                                                                                                                                                                                                              |
|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Manufacturer</b>                           | Coloplast A/S<br>Holtedam 1<br>3050 Humlebaek<br>Denmark                                                                                                                                                                                                                                                                                     |
| <b>Product</b>                                | Product family:<br>Biatain Foam Dressings                                                                                                                                                                                                                                                                                                    |
|                                               | Product name:<br>Biatain Non-adhesive Foam Dressing, Biatain Adhesive Foam Dressing, Biatain Soft-Hold Foam Dressing, Biatain Filler/Cavity Foam Dressing, Biatain Silicone Foam Dressing/Biatain Silicone, Biatain Silicone Lite Foam Dressing/Biatain Silicone Lite, Biatain Silicone Non-Border Foam Dressing/Biatain Silicone Non-Border |
| <b>Description</b>                            | On primary packaging: See attachment                                                                                                                                                                                                                                                                                                         |
|                                               | Global Medical Device Nomenclature code/name:<br>44970 Exudate-absorbent dressing, non-gel, non-antimicrobial<br>36226 Cavity-wound management dressing, non-antimicrobial                                                                                                                                                                   |
| <b>EC Product Class according to Annex IX</b> | Class: Sterile class IIb<br>Rule no.: 4                                                                                                                                                                                                                                                                                                      |
| <b>Notified Body</b>                          | DNV GL Presafe AS (2460)<br>Veritasveien 3, N-1363 Høvik, Norway                                                                                                                                                                                                                                                                             |
| <b>ID no.</b>                                 | 72                                                                                                                                                                                                                                                                                                                                           |

The undersigned, Director, Regulatory Affairs and Biosafety, declares that the following devices:  
Biatain Non-adhesive Foam Dressing, Biatain Adhesive Foam Dressing, Biatain Soft-Hold Foam Dressing, Biatain Filler/Cavity Foam Dressing, Biatain Silicone Foam Dressing/Biatain Silicone, Biatain Silicone Lite Foam Dressing/Biatain Silicone Lite, Biatain Silicone Non-Border Foam Dressing/Biatain Silicone Non-Border

conform to the relevant provisions of the European Communities' Council Directive 93/42/EEC and amendments and are in accordance with:

Annex II Conformity Assessment Procedure (full quality assurance system) as verified by the DNV GL Presafe AS (2460).

This product was originally CE-marked: 23/04/1998

Date: **15 DEC 2020** By:   
Joan Drejer  
Director, Regulatory Affairs and Biosafety

## Description on Primary Packaging for

### Product family:

Biatain Foam Dressings

### Product name:

Biatain Non-adhesive Foam Dressing, Biatain Adhesive Foam Dressing, Biatain Soft-Hold Foam Dressing, Biatain Filler/Cavity Foam Dressing, Biatain Silicone Foam Dressing/Biatain Silicone, Biatain Silicone Lite Foam Dressing/Biatain Silicone Lite, Biatain Silicone Non-Border Foam Dressing/Biatain Silicone Non-Border

| Item number    | Product name                        | Product description       | Date of the original CE-marking |
|----------------|-------------------------------------|---------------------------|---------------------------------|
| 33410/<br>3410 | Biatain Non-adhesive Foam Dressing  | 10cmx10cm, 4.4 mm         | 31-01-2008                      |
| 33412/<br>3412 | Biatain Non-adhesive Foam Dressing  | 10cmx20cm, 4.4 mm         | 31-01-2008                      |
| 33413/<br>3413 | Biatain Non-adhesive Foam Dressing  | 15cmx15cm, 4.4 mm         | 31-01-2008                      |
| 33416/<br>3416 | Biatain Non-adhesive Foam Dressing  | 20cmx20cm, 4.4 mm         | 31-01-2008                      |
| 36105/<br>6105 | Biatain Non-adhesive Foam Dressing  | 5cmx7cm, 4.4 mm           | 31-01-2008                      |
| 33451/<br>3451 | Biatain Cavity/Filler Foam Dressing | 5cmx8cm, 3 mm             | 10-03-2008                      |
| 33430/<br>3430 | Biatain Adhesive Foam Dressing      | 10cmx10cm, 3 mm           | 10-03-2008                      |
| 33420/<br>3420 | Biatain Adhesive Foam Dressing      | 12.5cm x 12.5cm, 3 mm     | 10-03-2008                      |
| 33421/<br>3421 | Biatain Adhesive Foam Dressing      | 15cmx15cm, 3 mm           | 10-03-2008                      |
| 33423/<br>3423 | Biatain Adhesive Foam Dressing      | 18cmx18cm, 3 mm           | 10-03-2008                      |
| 33462/<br>3462 | Biatain Adhesive Foam Dressing      | 7.5cm x 7.5cm, 3 mm       | 10-03-2008                      |
| 33426/<br>3426 | Biatain Adhesive Foam Dressing      | 18cmx28cm, 3 mm           | 10-03-2008                      |
| 33483/<br>3483 | Biatain Adhesive Foam Dressing      | Sacral, 17cmx17cm, 4,4 mm | 10-03-2008                      |
| 33485/<br>3485 | Biatain Adhesive Foam Dressing      | Sacral, 23cmx23cm, 4,4 mm | 10-03-2008                      |
| 33486/<br>3486 | Biatain Adhesive Foam Dressing      | Contour, 17cm, 3 mm       | 11-04-2008                      |
| 33488/<br>3488 | Biatain Adhesive Foam Dressing      | Heel, 19cmx20cm, 3 mm     | 10-03-2008                      |
| 33470/<br>3470 | Biatain Soft-Hold Foam Dressing     | 10cmx10cm, 4,4 mm         | 10-03-2008                      |
| 33472/<br>3472 | Biatain Soft-Hold Foam Dressing     | 10cmx20cm, 4,4 mm         | 10-03-2008                      |
| 33475/<br>3475 | Biatain Soft-Hold Foam Dressing     | 15cmx15cm, 4,4 mm         | 10-03-2008                      |

|                |                                                               |                         |            |
|----------------|---------------------------------------------------------------|-------------------------|------------|
| 33473/<br>3473 | Biatain Soft-Hold Foam Dressing                               | 5cmx7cm, 4,4 mm         | 10-03-2008 |
| 33434          | Biatain Silicone Foam Dressing/<br>Biatain Silicone           | 7.5cm x 7.5cm           | 06-11-2009 |
| 33435          | Biatain Silicone Foam Dressing/<br>Biatain Silicone           | 10cm x 10cm             | 14-06-2010 |
| 33436          | Biatain Silicone Foam Dressing/<br>Biatain Silicone           | 12.5cm x 12.5cm         | 06-11-2009 |
| 33437          | Biatain Silicone Foam Dressing/<br>Biatain Silicone           | 15cm x 15cm             | 06-11-2009 |
| 33438          | Biatain Silicone Foam Dressing/<br>Biatain Silicone           | 17.5cm x 17.5cm         | 06-11-2009 |
| 33444          | Biatain Silicone Lite Foam Dressing/<br>Biatain Silicone Lite | 7.5cm x 7.5 cm          | 23-11-2010 |
| 33445          | Biatain Silicone Lite Foam Dressing/<br>Biatain Silicone Lite | 10cm x 10cm             | 23-11-2010 |
| 33446          | Biatain Silicone Lite Foam Dressing/<br>Biatain Silicone Lite | 12.5cm x 12.5cm         | 23-11-2010 |
| 33487/<br>3487 | Biatain Adhesive Foam Dressing                                | Heel, 23 x 23 cm, 3 mm  | 04-03-2010 |
| 33429/<br>3429 | Biatain Soft-Hold Foam Dressing                               | 12.5cm x 12.5cm, 4.4 mm | 19-11-2008 |
| 33490/<br>3490 | Biatain Soft-Hold Foam Dressing                               | 10cmx10cm, 4.4 mm       | 10-03-2008 |
| 33495/<br>3495 | Biatain Soft-Hold Foam Dressing                               | 15cmx15cm, 4.4 mm       | 10-03-2008 |
| 33419/<br>3419 | Biatain Soft-Hold Foam Dressing                               | 17.5cm x 17.5cm, 4.4 mm | 19-09-2008 |
| 33492/<br>3492 | Biatain Soft-Hold Foam Dressing                               | 10cmx20cm, 4.4. mm      | 10-03-2008 |
| 33409/<br>3409 | Biatain Non-adhesive Foam Dressing                            | 10cmx10cm, 4.4 mm       | 31-01-2008 |
| 33411/<br>3411 | Biatain Non-adhesive Foam Dressing                            | 10cmx20cm, 4.4 mm       | 31-01-2008 |
| 33427/<br>3427 | Biatain Non-adhesive Foam Dressing                            | 12.5cmx12.5cm, 4.4 mm   | 31-01-2008 |
| 33414/<br>3414 | Biatain Non-adhesive Foam Dressing                            | 15cmx15cm, 4.4 mm       | 31-01-2008 |
| 33418/<br>3418 | Biatain Non-adhesive Foam Dressing                            | 17.5cmx17.5cm, 4.4 mm   | 31-01-2008 |
| 33417/<br>3417 | Biatain Non-adhesive Foam Dressing                            | 20cmx20cm, 4.4 mm       | 31-01-2008 |
| 33428/<br>3428 | Biatain Non-adhesive Foam Dressing                            | 21.5cmx21.5cm, 4.4 mm   | 31-01-2008 |
| 33443/<br>3443 | Biatain Adhesive Foam Dressing                                | 15cmx15cm, 4.4 mm       | 10-03-2008 |
| 33439/<br>3439 | Biatain Adhesive Foam Dressing                                | 17.5cmx17.5cm, 4.4 mm   | 10-03-2008 |
| 33489/<br>3489 | Biatain Adhesive Foam Dressing                                | Heel, 19cmx20cm, 3 mm   | 10-03-2008 |
| 33433/<br>3433 | Biatain Adhesive Foam Dressing                                | 12.5cmx12.5cm, 3 mm     | 10-03-2008 |
| 33440/<br>3440 | Biatain Adhesive Foam Dressing                                | 12.5cmx12.5cm, 4.4 mm   | 10-03-2008 |
| 33452          | Biatain Silicone Lite Foam Dressing/                          | 5cm x 5cm               | 12-11-2015 |

|       |                                                                           |                            |            |
|-------|---------------------------------------------------------------------------|----------------------------|------------|
|       | Biatain Silicone Lite                                                     |                            |            |
| 33453 | Biatain Silicone Lite Foam Dressing/<br>Biatain Silicone Lite             | 5cm x 12.5cm               | 12-11-2015 |
| 33400 | Biatain Silicone Foam Dressing/<br>Biatain Silicone                       | 10 cm x 20 cm              | 07-09-2016 |
| 33401 | Biatain Silicone Foam Dressing/<br>Biatain Silicone                       | 10 cm x 30 cm              | 07-09-2016 |
| 33404 | Biatain Silicone Foam Dressing/<br>Biatain Silicone                       | Sacral 15 cm x 19 cm       | 07-09-2016 |
| 33405 | Biatain Silicone Foam Dressing/<br>Biatain Silicone                       | Sacral 25 cm 25 cm         | 07-09-2016 |
| 33406 | Biatain Silicone Foam Dressing/<br>Biatain Silicone                       | Heel 18 cm x 18 cm         | 07-09-2016 |
| 33408 | Biatain Silicone Foam Dressing/<br>Biatain Silicone                       | Multishape 14 cm x 19.5 cm | 07-09-2016 |
| 39020 | Biatain Silicone Non-Border Foam<br>Dressing/ Biatain Silicone Non-Border | 5cm x 7.5cm                | 02-04-2020 |
| 39021 | Biatain Silicone Non-Border Foam<br>Dressing/ Biatain Silicone Non-Border | 7.5cm x 7.5cm              | 02-04-2020 |
| 39022 | Biatain Silicone Non-Border Foam<br>Dressing/ Biatain Silicone Non-Border | 10cm x 10cm                | 02-04-2020 |
| 39023 | Biatain Silicone Non-Border Foam<br>Dressing/ Biatain Silicone Non-Border | 12.5cm x 12.5cm            | 02-04-2020 |
| 39024 | Biatain Silicone Non-Border Foam<br>Dressing/ Biatain Silicone Non-Border | 10cm x 20cm                | 02-04-2020 |
| 39025 | Biatain Silicone Non-Border Foam<br>Dressing/ Biatain Silicone Non-Border | 15cm x 15cm                | 02-04-2020 |
| 39026 | Biatain Silicone Non-Border Foam<br>Dressing/ Biatain Silicone Non-Border | 20cm x 20cm                | 02-04-2020 |
| 39027 | Biatain Silicone Non-Border Foam<br>Dressing/ Biatain Silicone Non-Border | 17.5cm x 17.5cm            | 02-04-2020 |
| 39028 | Biatain Silicone Non-Border Foam<br>Dressing/ Biatain Silicone Non-Border | 21.5cm x 21.5cm            | 02-04-2020 |
| 39000 | Biatain Silicone Foam Dressing/<br>Biatain Silicone                       | Sacral 25 cm x 25 cm       | 30-10-2020 |
| 39001 | Biatain Silicone Foam Dressing/<br>Biatain Silicone                       | Sacral 15 cm x 19 cm       | 30-10-2020 |
| 39010 | Biatain Silicone Foam Dressing/<br>Biatain Silicone                       | Multishape 14 cm x 19.5 cm | 30-10-2020 |

Date: **15 DEC 2020** By:   
Joan Drejer  
Director, Regulatory Affairs and Biosafety