

## 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 |
| <b>Description</b>                            | On primary packaging: See attachment                                                                                                                                                                                                                                  |
|                                               | Global Medical Device Nomenclature code/name:<br>44970 Exudate-absorbent dressing, non-gel<br>36226 Cavity-wound management dressing                                                                                                                                  |
| <b>EC Product Class according to Annex IX</b> | Class: Sterile class IIb<br>Rule no.: 4                                                                                                                                                                                                                               |
| <b>Notified Body</b>                          | Presafe Denmark A/S - (0543)<br>Tuborg Parkvej 8, DK-2900 Hellerup, Denmark                                                                                                                                                                                           |
| <b>ID no.</b>                                 | 72                                                                                                                                                                                                                                                                    |

The undersigned, Director, Regulatory and EHS Affairs, 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  
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 Presafe Denmark A/S - (0543).

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

Date: **30 NOV 2017**

By:

  
Caroline Jane Allen

Director, Regulatory and EHS Affairs

## 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

| Item number | Product name                        | Product description              | Date of the original CE-marking |
|-------------|-------------------------------------|----------------------------------|---------------------------------|
| 03410       | Biatain Non-adhesive Foam Dressing  | 10cmx10cm, 4.4 mm                | 23-04-1998                      |
| 03413       | Biatain Non-adhesive Foam Dressing  | 15cmx15cm, 4.4 mm                | 23-04-1998                      |
| 03416       | Biatain Non-adhesive Foam Dressing  | 20cmx20cm, 4.4 mm                | 23-04-1998                      |
| 03420       | Biatain Adhesive Foam Dressing      | 12.5cm x 12.5cm, 3 mm            | 23-04-1998                      |
| 03421       | Biatain Adhesive Foam Dressing      | 15cmx15cm, 3 mm                  | 23-04-1998                      |
| 03423       | Biatain Adhesive Foam Dressing      | 18cmx18cm, 3 mm                  | 23-04-1998                      |
| 03426       | Biatain Adhesive Foam Dressing      | 18cmx28cm, 3 mm                  | 02-05-2000                      |
| 03483       | Biatain Adhesive Foam Dressing      | Sacral junior, 17cmx17cm, 4.4 mm | 15-02-2001                      |
| 03485       | Biatain Adhesive Foam Dressing      | Sacral, 23cmx23cm, 4.4 mm        | 09-03-2000                      |
| 03488       | Biatain Adhesive Foam Dressing      | Heel, 19cmx20cm, 3 mm            | 14-03-2001                      |
| 03451       | Biatain Filler/Cavity Foam Dressing | 5cmx8cm, 3 mm                    | 16-12-2002                      |
| 33410       | Biatain Non-adhesive Foam Dressing  | 10cmx10cm, 4.4 mm                | 31-01-2008                      |
| 33412       | Biatain Non-adhesive Foam Dressing  | 10cmx20cm, 4.4 mm                | 31-01-2008                      |
| 33413       | Biatain Non-adhesive Foam Dressing  | 15cmx15cm, 4.4 mm                | 31-01-2008                      |
| 33416       | Biatain Non-adhesive Foam Dressing  | 20cmx20cm, 4.4 mm                | 31-01-2008                      |
| 36105       | Biatain Non-adhesive Foam Dressing  | 5cmx7cm, 4.4 mm                  | 31-01-2008                      |
| 33451       | Biatain Cavity/Filler Foam Dressing | 5cmx8cm, 3 mm                    | 10-03-2008                      |
| 33430       | Biatain Adhesive Foam Dressing      | 10cmx10cm, 3 mm                  | 10-03-2008                      |
| 33420       | Biatain Adhesive Foam Dressing      | 12.5cm x 12.5cm, 3 mm            | 10-03-2008                      |
| 33421       | Biatain Adhesive Foam Dressing      | 15cmx15cm, 3 mm                  | 10-03-2008                      |
| 33423       | Biatain Adhesive Foam Dressing      | 18cmx18cm, 3 mm                  | 10-03-2008                      |
| 33462       | Biatain Adhesive Foam Dressing      | 7.5cm x 7.5cm, 3 mm              | 10-03-2008                      |
| 33426       | Biatain Adhesive Foam Dressing      | 18cmx28cm, 3 mm                  | 10-03-2008                      |
| 33483       | Biatain Adhesive Foam Dressing      | Sacral, 17cmx17cm, 4.4 mm        | 10-03-2008                      |

|       |                                                               |                           |            |
|-------|---------------------------------------------------------------|---------------------------|------------|
| 33485 | Biatain Adhesive Foam Dressing                                | Sacral, 23cmx23cm, 4,4 mm | 10-03-2008 |
| 33486 | Biatain Adhesive Foam Dressing                                | Contour, 17cm, 3 mm       | 11-04-2008 |
| 33488 | Biatain Adhesive Foam Dressing                                | Heel, 19cmx20cm, 3 mm     | 10-03-2008 |
| 33470 | Biatain Soft-Hold Foam Dressing                               | 10cmx10cm, 4,4 mm         | 10-03-2008 |
| 33472 | Biatain Soft-Hold Foam Dressing                               | 10cmx20cm, 4,4 mm         | 10-03-2008 |
| 33475 | Biatain Soft-Hold Foam Dressing                               | 15cmx15cm, 4,4 mm         | 10-03-2008 |
| 33473 | 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 | Biatain Adhesive Foam Dressing                                | Heel, 23 x 23 cm, 3 mm    | 04-03-2010 |
| 33429 | Biatain Soft-Hold Foam Dressing                               | 12.5cm x 12.5cm, 4.4 mm   | 19-11-2008 |
| 33490 | Biatain Soft-Hold Foam Dressing                               | 10cmx10cm, 4.4.mm         | 10-03-2008 |
| 33495 | Biatain Soft-Hold Foam Dressing                               | 15cmx15cm, 4.4 mm         | 10-03-2008 |
| 33419 | Biatain Soft-Hold Foam Dressing                               | 17.5cm x 17.5cm, 4.4 mm   | 19-09-2008 |
| 33492 | Biatain Soft-Hold Foam Dressing                               | 10cmx20cm, 4.4. mm        | 10-03-2008 |
| 33409 | Biatain Non-adhesive Foam Dressing                            | 10cmx10cm, 4.4 mm         | 31-01-2008 |
| 33411 | Biatain Non-adhesive Foam Dressing                            | 10cmx20cm, 4.4 mm         | 31-01-2008 |
| 33427 | Biatain Non-adhesive Foam Dressing                            | 12.5cmx12.5cm, 4.4 mm     | 31-01-2008 |
| 33414 | Biatain Non-adhesive Foam Dressing                            | 15cmx15cm, 4.4 mm         | 31-01-2008 |
| 33418 | Biatain Non-adhesive Foam Dressing                            | 17.5cmx17.5cm, 4.4 mm     | 31-01-2008 |
| 33417 | Biatain Non-adhesive Foam Dressing                            | 20cmx20cm, 4.4 mm         | 31-01-2008 |
| 33428 | Biatain Non-adhesive Foam Dressing                            | 21.5cmx21.5cm, 4.4 mm     | 31-01-2008 |
| 33443 | Biatain Adhesive Foam Dressing                                | 15cmx15cm, 4.4 mm         | 10-03-2008 |
| 33439 | Biatain Adhesive Foam Dressing                                | 17.5cmx17.5cm, 4.4 mm     | 10-03-2008 |
| 33489 | Biatain Adhesive Foam Dressing                                | Heel, 19cmx20cm, 3 mm     | 10-03-2008 |
| 33433 | Biatain Adhesive Foam Dressing                                | 12.5cmx12.5cm, 3 mm       | 10-03-2008 |
| 33440 | Biatain Adhesive Foam Dressing                                | 12.5cmx12.5cm, 4.4 mm     | 10-03-2008 |

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|-------|---------------------------------------------------------------|-------------------------|------------|
| 33452 | Biatain Silicone Lite Foam Dressing/<br>Biatain Silicone Lite | 5cm x 5cm               | 12-11-2015 |
| 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 | 07-09-2016 |

Date: **30 NOV 2017**

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