



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

<b>Manufacturer</b>	Coloplast A/S Holtedam 1 3050 Humlebaek Denmark
<b>Product</b>	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
<b>Description</b>	On primary packaging: See attachment
	Global Medical Device Nomenclature code/name: 44970 Exudate-absorbent dressing, non-gel, non-antimicrobial 36226 Cavity-wound management dressing, non-antimicrobial
<b>EC Product Class according to Annex IX</b>	Class: Sterile class IIb Rule no.: 4
<b>Notified Body</b>	DNV GL Presafe AS (2460) 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/ 3410	Biatain Non-adhesive Foam Dressing	10cmx10cm, 4.4 mm	31-01-2008
33412/ 3412	Biatain Non-adhesive Foam Dressing	10cmx20cm, 4.4 mm	31-01-2008
33413/ 3413	Biatain Non-adhesive Foam Dressing	15cmx15cm, 4.4 mm	31-01-2008
33416/ 3416	Biatain Non-adhesive Foam Dressing	20cmx20cm, 4.4 mm	31-01-2008
36105/ 6105	Biatain Non-adhesive Foam Dressing	5cmx7cm, 4.4 mm	31-01-2008
33451/ 3451	Biatain Cavity/Filler Foam Dressing	5cmx8cm, 3 mm	10-03-2008
33430/ 3430	Biatain Adhesive Foam Dressing	10cmx10cm, 3 mm	10-03-2008
33420/ 3420	Biatain Adhesive Foam Dressing	12.5cm x 12.5cm, 3 mm	10-03-2008
33421/ 3421	Biatain Adhesive Foam Dressing	15cmx15cm, 3 mm	10-03-2008
33423/ 3423	Biatain Adhesive Foam Dressing	18cmx18cm, 3 mm	10-03-2008
33462/ 3462	Biatain Adhesive Foam Dressing	7.5cm x 7.5cm, 3 mm	10-03-2008
33426/ 3426	Biatain Adhesive Foam Dressing	18cmx28cm, 3 mm	10-03-2008
33483/ 3483	Biatain Adhesive Foam Dressing	Sacral, 17cmx17cm, 4,4 mm	10-03-2008
33485/ 3485	Biatain Adhesive Foam Dressing	Sacral, 23cmx23cm, 4,4 mm	10-03-2008
33486/ 3486	Biatain Adhesive Foam Dressing	Contour, 17cm, 3 mm	11-04-2008
33488/ 3488	Biatain Adhesive Foam Dressing	Heel, 19cmx20cm, 3 mm	10-03-2008
33470/ 3470	Biatain Soft-Hold Foam Dressing	10cmx10cm, 4,4 mm	10-03-2008
33472/ 3472	Biatain Soft-Hold Foam Dressing	10cmx20cm, 4,4 mm	10-03-2008
33475/ 3475	Biatain Soft-Hold Foam Dressing	15cmx15cm, 4,4 mm	10-03-2008

33473/ 3473	Biatain Soft-Hold Foam Dressing	5cmx7cm, 4,4 mm	10-03-2008
33434	Biatain Silicone Foam Dressing/ Biatain Silicone	7.5cm x 7.5cm	06-11-2009
33435	Biatain Silicone Foam Dressing/ Biatain Silicone	10cm x 10cm	14-06-2010
33436	Biatain Silicone Foam Dressing/ Biatain Silicone	12.5cm x 12.5cm	06-11-2009
33437	Biatain Silicone Foam Dressing/ Biatain Silicone	15cm x 15cm	06-11-2009
33438	Biatain Silicone Foam Dressing/ Biatain Silicone	17.5cm x 17.5cm	06-11-2009
33444	Biatain Silicone Lite Foam Dressing/ Biatain Silicone Lite	7.5cm x 7.5 cm	23-11-2010
33445	Biatain Silicone Lite Foam Dressing/ Biatain Silicone Lite	10cm x 10cm	23-11-2010
33446	Biatain Silicone Lite Foam Dressing/ Biatain Silicone Lite	12.5cm x 12.5cm	23-11-2010
33487/ 3487	Biatain Adhesive Foam Dressing	Heel, 23 x 23 cm, 3 mm	04-03-2010
33429/ 3429	Biatain Soft-Hold Foam Dressing	12.5cm x 12.5cm, 4.4 mm	19-11-2008
33490/ 3490	Biatain Soft-Hold Foam Dressing	10cmx10cm, 4.4 mm	10-03-2008
33495/ 3495	Biatain Soft-Hold Foam Dressing	15cmx15cm, 4.4 mm	10-03-2008
33419/ 3419	Biatain Soft-Hold Foam Dressing	17.5cm x 17.5cm, 4.4 mm	19-09-2008
33492/ 3492	Biatain Soft-Hold Foam Dressing	10cmx20cm, 4.4 mm	10-03-2008
33409/ 3409	Biatain Non-adhesive Foam Dressing	10cmx10cm, 4.4 mm	31-01-2008
33411/ 3411	Biatain Non-adhesive Foam Dressing	10cmx20cm, 4.4 mm	31-01-2008
33427/ 3427	Biatain Non-adhesive Foam Dressing	12.5cmx12.5cm, 4.4 mm	31-01-2008
33414/ 3414	Biatain Non-adhesive Foam Dressing	15cmx15cm, 4.4 mm	31-01-2008
33418/ 3418	Biatain Non-adhesive Foam Dressing	17.5cmx17.5cm, 4.4 mm	31-01-2008
33417/ 3417	Biatain Non-adhesive Foam Dressing	20cmx20cm, 4.4 mm	31-01-2008
33428/ 3428	Biatain Non-adhesive Foam Dressing	21.5cmx21.5cm, 4.4 mm	31-01-2008
33443/ 3443	Biatain Adhesive Foam Dressing	15cmx15cm, 4.4 mm	10-03-2008
33439/ 3439	Biatain Adhesive Foam Dressing	17.5cmx17.5cm, 4.4 mm	10-03-2008
33489/ 3489	Biatain Adhesive Foam Dressing	Heel, 19cmx20cm, 3 mm	10-03-2008
33433/ 3433	Biatain Adhesive Foam Dressing	12.5cmx12.5cm, 3 mm	10-03-2008
33440/ 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/ Biatain Silicone Lite	5cm x 12.5cm	12-11-2015
33400	Biatain Silicone Foam Dressing/ Biatain Silicone	10 cm x 20 cm	07-09-2016
33401	Biatain Silicone Foam Dressing/ Biatain Silicone	10 cm x 30 cm	07-09-2016
33404	Biatain Silicone Foam Dressing/ Biatain Silicone	Sacral 15 cm x 19 cm	07-09-2016
33405	Biatain Silicone Foam Dressing/ Biatain Silicone	Sacral 25 cm 25 cm	07-09-2016
33406	Biatain Silicone Foam Dressing/ Biatain Silicone	Heel 18 cm x 18 cm	07-09-2016
33408	Biatain Silicone Foam Dressing/ Biatain Silicone	Multishape 14 cm x 19.5 cm	07-09-2016
39020	Biatain Silicone Non-Border Foam Dressing/ Biatain Silicone Non-Border	5cm x 7.5cm	02-04-2020
39021	Biatain Silicone Non-Border Foam Dressing/ Biatain Silicone Non-Border	7.5cm x 7.5cm	02-04-2020
39022	Biatain Silicone Non-Border Foam Dressing/ Biatain Silicone Non-Border	10cm x 10cm	02-04-2020
39023	Biatain Silicone Non-Border Foam Dressing/ Biatain Silicone Non-Border	12.5cm x 12.5cm	02-04-2020
39024	Biatain Silicone Non-Border Foam Dressing/ Biatain Silicone Non-Border	10cm x 20cm	02-04-2020
39025	Biatain Silicone Non-Border Foam Dressing/ Biatain Silicone Non-Border	15cm x 15cm	02-04-2020
39026	Biatain Silicone Non-Border Foam Dressing/ Biatain Silicone Non-Border	20cm x 20cm	02-04-2020
39027	Biatain Silicone Non-Border Foam Dressing/ Biatain Silicone Non-Border	17.5cm x 17.5cm	02-04-2020
39028	Biatain Silicone Non-Border Foam Dressing/ Biatain Silicone Non-Border	21.5cm x 21.5cm	02-04-2020
39000	Biatain Silicone Foam Dressing/ Biatain Silicone	Sacral 25 cm x 25 cm	30-10-2020
39001	Biatain Silicone Foam Dressing/ Biatain Silicone	Sacral 15 cm x 19 cm	30-10-2020
39010	Biatain Silicone Foam Dressing/ Biatain Silicone	Multishape 14 cm x 19.5 cm	30-10-2020

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