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

Manufacturer	Coloplast A/S Holtedam 1 3050 Humlebaek Denmark
Product	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
Description	On primary packaging: See attachment
	Global Medical Device Nomenclature code/name: 44970 Exudate-absorbent dressing, non-gel 36226 Cavity-wound management dressing
EC Product Class according to Annex IX	Class: Sterile class IIb Rule no.: 4
Notified Body	Presafe Denmark A/S - (0543) Tuborg Parkvej 8, DK-2900 Hellerup, Denmark
ID no.	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/ 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	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

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

Date: 30 NOV 2017 By: _____

Caroline Jane Allen
Director, Regulatory and EHS Affairs