



**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: Antibacterial Foam Dressings
	Product name: Biatain Ag Non-adhesive Foam Dressing, Biatain Ag Adhesive Foam Dressing, Biatain Ag Filler/Cavity Foam Dressing, Biatain Silicone Ag
Description	On primary packaging: See attachment
	Global Medical Device Nomenclature code/name: 48124 Exudate-absorbent dressing, non-gel, antimicrobial 36226 Cavity-wound management dressing, non-antimicrobial
EC Product Class according to Annex IX	Class: Sterile class III Rule no.: 13
Notified Body	DNV GL Presafe AS (2460) Veritasveien 3, N-1363 Høvik, Norway
ID no.	70

The undersigned, Director, Global Regulatory Affairs, declares that the following devices:
Biatain Ag Non-adhesive Foam Dressing, Biatain Ag Adhesive Foam Dressing, Biatain Ag Filler/Cavity
Foam Dressing, Biatain Silicone Ag
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: 15/07/2002

Date: 18 Dec 2020

By: _____

Joan Drejer

Director, Global Regulatory Affairs

Description on Primary Packaging for

Product family:

Antibacterial Foam Dressings

Product name:

Biatain Ag Non-adhesive Foam Dressing, Biatain Ag Adhesive Foam Dressing, Biatain Ag Filler/Cavity Foam Dressing, Biatain Silicone Ag

Item number	Product name	Product description	Date of the original CE-marking
39622/ 9622	Biatain Ag Non-adhesive Foam Dressing/Biatain Ag Non-adhesive	10cmx10cm, 4.4 mm	10-03-2008
39623/ 9623	Biatain Ag Non-adhesive Foam Dressing/Biatain Ag Non-adhesive	10cmx20cm, 4.4 mm	10-03-2008
39625/ 9625	Biatain Ag Non-adhesive Foam Dressing/Biatain Ag Non-adhesive	15cmx15cm, 4.4 mm	10-03-2008
39626/ 9626	Biatain Ag Non-adhesive Foam Dressing/Biatain Ag Non-adhesive	20cmx20cm, 4.4 mm	10-03-2008
35105/ 5105	Biatain Ag Non-adhesive Foam Dressing/Biatain Ag Non-adhesive	5cmx7cm, 4.4 mm	10-03-2008
39628/ 9628	Biatain Ag Filler/Cavity Foam Dressing/Biatain Ag Filler/Cavity	5cmx8cm, 3 mm	10-03-2008
39632/ 9632	Biatain Ag Adhesive Foam Dressing/Biatain Ag Adhesive	12.5cmx12.5cm, 3 mm	10-03-2008
33464/ 3464	Biatain Ag Adhesive Foam Dressing/Biatain Ag Adhesive	15cmx15cm, 3 mm	10-03-2008
39635/ 9635	Biatain Ag Adhesive Foam Dressing/Biatain Ag Adhesive	18cmx18cm, 3 mm	10-03-2008
39631/ 9631	Biatain Ag Adhesive Foam Dressing/Biatain Ag Adhesive	7.5cmx7.5cm, 3 mm	10-03-2008
39641/ 9641	Biatain Ag Adhesive Foam Dressing/Biatain Ag Adhesive	Sacral, 23cmx23cm, 4.4 mm	10-03-2008
39643/ 9643	Biatain Ag Adhesive Foam Dressing/Biatain Ag Adhesive	Heel, 19cmx20cm, 3 mm	10-03-2008
33448	Biatain Ag Non-adhesive Foam Dressing/Biatain Ag Non-adhesive	10cmx12cm, 4.4 mm	20-04-2009
33449	Biatain Ag Non-adhesive Foam Dressing/Biatain Ag Non-adhesive	15cmx15cm, 4.4 mm	20-04-2009
33569/ 3569	Biatain Ag Non-adhesive Foam Dressing/Biatain Ag Non-adhesive	12.5cmx12.5cm, 4.4 mm	03-02-2009
33567/ 3567	Biatain Ag Non-adhesive Foam Dressing/Biatain Ag Non-adhesive	17.5cmx17.5cm, 4.4 mm	03-02-2009
33522/ 3522	Biatain Ag Adhesive Foam Dressing/Biatain Ag Adhesive	Sacral, 23cmx23cm, 4.4 mm	11-04-2008
33521/ 3521	Biatain Ag Adhesive Foam Dressing/Biatain Ag Adhesive	Sacral, 17cmx17cm, 4.4 mm	11-04-2008
33541/ 3541	Biatain Ag Adhesive Foam Dressing/Biatain Ag Adhesive	Sacral, 23cmx23cm, 3 mm	03-02-2009
33523/ 3523	Biatain Ag Adhesive Foam Dressing/Biatain Ag Adhesive	Heel, 19cmx20cm, 3 mm	11-04-2008

33543/ 3543	Biatain Ag Adhesive Foam Dressing/Biatain Ag Adhesive	Heel, 19cmx20cm, 3 mm	03-02-2009
33459/ 3459	Biatain Ag Adhesive Foam Dressing/Biatain Ag Adhesive	15cmx15cm, 3 mm	09-01-2009
33461/ 3461	Biatain Ag Adhesive Foam Dressing/Biatain Ag Adhesive	17.5cmx17.5cm, 3 mm	03-02-2009
33454/ 3454	Biatain Ag Non-adhesive Foam Dressing/Biatain Ag Non-adhesive	10cmx10cm, 4.4 mm	11-04-2008
33455/ 3455	Biatain Ag Non-adhesive Foam Dressing/Biatain Ag Non-adhesive	15cmx15cm, 4.4 mm	11-04-2008
39636	Biatain Silicone Ag Foam Dressing/Biatain Silicone Ag	7.5cmx7.5cm	07-02-2011
39637	Biatain Silicone Ag Foam Dressing/Biatain Silicone Ag	10cmx10cm	07-02-2011
39638	Biatain Silicone Ag Foam Dressing/Biatain Silicone Ag	12.5cmx12.5cm	07-02-2011
39639	Biatain Silicone Ag Foam Dressing/Biatain Silicone Ag	15cmx15cm	07-02-2011
39640	Biatain Silicone Ag Foam Dressing/Biatain Silicone Ag	17.5cmx17.5cm	07-02-2011
39644	Biatain Silicone Ag Foam Dressing/Biatain Silicone Ag	10 cm x 20 cm	29-09-2017
39645	Biatain Silicone Ag Foam Dressing/Biatain Silicone Ag	10 cm x 30 cm	29-09-2017
39650	Biatain Silicone Ag Foam Dressing/Biatain Silicone Ag	Sacral 15 cm x 19 cm	29-09-2017
39651	Biatain Silicone Ag Foam Dressing/Biatain Silicone Ag	Sacral 25 cm x 25 cm	29-09-2017
39652	Biatain Silicone Ag Foam Dressing/Biatain Silicone Ag	Heel 18 cm x 18 cm	29-09-2017

Date: 18 Dec 2020 By: 
Joan Drejer
Director, Global Regulatory Affairs