



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: Gelling Fiber Wound Dressing
	Product name: Biatain Fiber
Description	On primary packaging: See attachment
	Global Medical Device Nomenclature code/name: 43186 Exudate-absorbent dressing, hydrophilic-gel
EC Product Class according to Annex IX	Class: Sterile class IIb Rule no.: 4
Notified Body	DNV GL Presafe AS (2460) Veritasveien 3, N-1363 Høvik, Norway
ID no.	479

The undersigned, Director, Regulatory Affairs and Biosafety, declares that the following devices:
Biatain Fiber
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: 05/11/2019

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

Description on Primary Packaging for

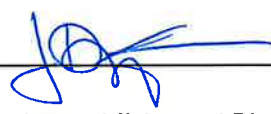
Product family:

Gelling Fiber Wound Dressing

Product name:

Biatain Fiber

Item number	Product name	Product description	Date of the original CE-marking
33501	Biatain® Fiber 5cm x 5cm / 2in x 2in	Quadratic dressing with dimensions 5cm x 5cm / 2in x 2in	05-11-2019
33502	Biatain® Fiber 5cm x 6cm / 2in x 2.5in	Quadratic dressing with dimensions 5cm x 6cm / 2in x 2.5in	05-11-2019
33503	Biatain® Fiber 10cm x 10cm / 4in x 4in	Quadratic dressing with dimensions 10cm x 10cm / 4in x 4in	05-11-2019
33504	Biatain® Fiber 10cm x 12cm / 4in x 5in	Quadratic dressing with dimensions 10cm x 12cm / 4in x 5in	05-11-2019
33505	Biatain® Fiber 12.5cm x 12.5cm / 5in x 5in	Quadratic dressing with dimensions 12.5cm x 12.5cm / 5in x 5in	05-11-2019
33506	Biatain® Fiber 15cm x 15cm / 6in x 6in	Quadratic dressing with dimensions 15cm x 15cm / 6in x 6in	05-11-2019
33507	Biatain® Fiber 19cm x 25cm / 7.5in x 10in	Quadratic dressing with dimensions 19cm x 25cm / 7.5in x 10in	05-11-2019
33508	Biatain® Fiber 2.5cm x 46cm / 1in x 18in	Ribbon dressing with the dimensions 2.5cm x 46cm / 1in x 18in	05-11-2019
33509	Biatain® Fiber 3.5cm x 46cm / 1.5in x 18in	Ribbon dressing with the dimensions 3.5cm x 46cm / 1.5in x 18in	05-11-2019

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