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: Hydrocapillary Dressings
	Product name: Biatain Super Adhesive Dressing, Biatain Super Non-Adhesive Dressing
Description	On primary packaging: See attachment
	Global Medical Device Nomenclature code/name: 44970 Exudate-absorbent dressing, non-gel, non-antimicrobial
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.	73

The undersigned, Director, Global Regulatory Affairs, declares that the following devices:
Biatain Super Adhesive Dressing, Biatain Super Non-Adhesive Dressing
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: 15/08/2001

Date: 15 DEC 2020 By: _____

Joan Drejer
Director, Global Regulatory Affairs

Description on Primary Packaging for

Product family:
Hydrocapillary Dressings

Product name:
Biatain Super Adhesive Dressing, Biatain Super Non-Adhesive Dressing

Item number	Product name	Product description	Date of the original CE-marking
04610/ 46100	Biatain Super Adhesive /Alione Adhesive	Hydrocapillary Dressing 10 cm x 10 cm	15-08-2001
04612/ 46120	Biatain Super Adhesive /Alione Adhesive	Hydrocapillary Dressing 12.5 cm x 12.5 cm	15-08-2001
04615/ 46150	Biatain Super Adhesive /Alione Adhesive	Hydrocapillary Dressing 15 cm x 15 cm	15-08-2001
04620/ 46200	Biatain Super Adhesive /Alione Adhesive	Hydrocapillary Dressing 20 cm x 20 cm	18-04-2002
04625/ 46250	Biatain Super Adhesive /Alione Adhesive	Hydrocapillary Dressing 12 cm x 20 cm	18-08-2003
04630/ 46300	Biatain Super Non-Adhesive /Alione Non-Adhesive	Hydrocapillary Dressing 10 cm x 10 cm	12-02-2002
04632/ 46320	Biatain Super Non-Adhesive /Alione Non-Adhesive	Hydrocapillary Dressing 12.5 cm x 12.5 cm	12-02-2002
04635/ 46350	Biatain Super Non-Adhesive /Alione Non-Adhesive	Hydrocapillary Dressing 15 cm x 15 cm	12-02-2002
04639/ 46390	Biatain Super Non-Adhesive /Alione Non-Adhesive	Hydrocapillary Dressing 20 cm x 20 cm	18-04-2002
04645/ 46450	Biatain Super Non-Adhesive /Alione Non-Adhesive	Hydrocapillary Dressing 12 cm x 20 cm	18-08-2003

Date: 15 DEC 2020 By: _____

Joan Drejer
Director, Global Regulatory Affairs