

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: Comfeel Wound Dressings
	Product name: Comfeel Plus Ulcer Dressing, Comfeel Plus Sacral Dressing, Comfeel Plus Dressing - France, Comfeel Plus Contour Dressing, Comfeel Plus Pressure Relieving Dressing, Comfeel Plus Transparent Dressing, Comfeel Plus Sacral Transparent Dressing, Comfeel Plus Pressure Relief, Comfeel Plus, Comfeel Plus Sacral, Comfeel Plus Contour, Comfeel Plus Transparent, Comfeel Plus Transparent Sacral
Description	On primary packaging: See attachment
	Global Medical Device Nomenclature code/name: 47764 Wound Hydrogel dressing, sterile
	43186 Exudate-absorbent dressing, hydrophilic-gel
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.	115

The undersigned, Director, Global Regulatory Affairs, declares that the following devices:

Comfeel Plus Ulcer Dressing, Comfeel Plus Sacral Dressing, Comfeel Plus Dressing - France, Comfeel Plus Contour Dressing, Comfeel Plus Pressure Relieving Dressing, Comfeel Plus Transparent Dressing, Comfeel Plus Sacral Transparent Dressing, Comfeel Plus Pressure Relief, Comfeel Plus, Comfeel Plus Sacral, Comfeel Plus Contour, Comfeel Plus Transparent, Comfeel Plus Transparent Sacral 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: 14/12/1994

Date: **26 NOV 2018**

By: _____

Joan Drejer

Director, Global Regulatory Affairs

Description on Primary Packaging for

Product family:

Comfeel Wound Dressings

Product name:

Comfeel Plus Ulcer Dressing, Comfeel Plus Sacral Dressing, Comfeel Plus Dressing - France, Comfeel Plus Contour Dressing, Comfeel Plus Pressure Relieving Dressing, Comfeel Plus Transparent Dressing, Comfeel Plus Sacral Transparent Dressing, Comfeel Plus Pressure Relief, Comfeel Plus, Comfeel Plus Sacral, Comfeel Plus Contour, Comfeel Plus Transparent, Comfeel Plus Transparent Sacral

Item number	Product name	Product description	Date of the original CE-marking
3110 / 03110	Comfeel Plus Ulcer Dressing	10cmx10cm	20-10-1997
3115 / 03115	Comfeel Plus Ulcer Dressing	15cmx15cm	20-10-1997
3120 / 03120	Comfeel Plus Ulcer Dressing	20cmx20cm	20-10-1997
3146 / 03146	Comfeel Plus Ulcer Dressing	4cmx6cm	20-10-1997
3285 / 03285	Comfeel Plus Sacral Dressing	18cmx20cm	25-11-2003
3270 / 03270	Comfeel Plus Contour Dressing	6cmx8cm	14-12-1994
3273 / 03273	Comfeel Plus Contour Dressing	9cmx11cm	14-12-1994
3280 / 03280	Comfeel Plus Contour Dressing	6cmx8cm	31-07-1995
3283 / 03283	Comfeel Plus Contour Dressing	9cmx11cm	31-07-1995
3282 / 03282	Comfeel Plus Contour Dressing	9cmx12cm	31-07-1995
3290 / 03290	Comfeel Plus Dressing - France	10cmx10cm	14-12-1994
3291 / 03291	Comfeel Plus Dressing - France	12,5cmx12,5cm	23-07-2008
3293 / 03293	Comfeel Plus Dressing - France	15cmx15cm	14-12-1994
3294 / 03294	Comfeel Plus Dressing - France	17,5cmx17,5cm	23-07-2008
3296 / 03296	Comfeel Plus Dressing - France	20cmx20cm	14-12-1994
3297 / 03297	Comfeel Plus Dressing - France	21,5cmx21,5cm	08-10-2008
3350 / 03350	Comfeel Plus Pressure Relieving Dressing	Ø7cm	31-07-1995
3353 / 03350	Comfeel Plus Pressure Relieving Dressing	Ø10cm	31-07-1995
3356 / 03356	Comfeel Plus Pressure Relieving Dressing	Ø15cm	31-07-1995

3530 / 03530	Comfeel Plus Transparent Dressing	5cmx7cm	19-12-1994
3533 / 03533	Comfeel Plus Transparent Dressing	10cmx10cm	19-12-1994
3517 / 03517	Comfeel Plus Transparent Dressing	12,5cmx12,5cm	22-07-2008
3536 / 03536	Comfeel Plus Transparent Dressing	9cmx14cm	19-12-1994
3537 / 03537	Comfeel Plus Transparent Dressing	9cmx25cm	19-12-1994
3539 / 03539	Comfeel Plus Transparent Dressing	15cmx15cm	19-12-1994
3518 03518	Comfeel Plus Transparent Dressing	17,5cmx17,5cm	22-07-2008
3542 / 03542	Comfeel Plus Transparent Dressing	15cmx20cm	19-12-1994
3545 / 03545	Comfeel Plus Transparent Dressing	20cmx20cm	19-12-1994
3538/ 03538	Comfeel Plus Transparent Dressing	21,5cmx21,5cm	08-10-2008
3547/ 03547	Comfeel Plus Transparent Dressing	5cmx15cm	19-12-1994
3548/ 03548	Comfeel Plus Transparent Dressing	5cmx25cm	19-12-1994
3586/ 03586	Comfeel Plus Sacral Transparent Dressing	17cmx17cm	02-01-1998
33350	Comfeel Plus Pressure Relief	7 cm	08-03-2016
33353	Comfeel Plus Pressure Relief	10 cm	08-03-2016
33356	Comfeel Plus Pressure Relief	15 cm	08-03-2016
33146	Comfeel Plus	4 cm x 6 cm	21-04-2016
33110	Comfeel Plus	10 cm x 10 cm	21-04-2016
33291	Comfeel Plus	13 cm x 13 cm	21-04-2016
33115	Comfeel Plus	15 cm x 15 cm	21-04-2016
33294	Comfeel Plus	18 cm x 18 cm	21-04-2016
33120	Comfeel Plus	20 cm x 20 cm	21-04-2016
33297	Comfeel Plus	22.5 cm x 22.5 cm	21-04-2016
33285	Comfeel Plus, Sacral	17 cm x 17 cm	21-04-2016
33280	Comfeel Plus Contour	6 cm x 8 cm	29-04-2016
33283	Comfeel Plus Contour	9 cm x 11 cm	21-04-2016
33530	Comfeel Plus Transparent	5 cm x 7 cm	18-08-2016
33547	Comfeel Plus Transparent	5 cm x 15 cm	18-08-2016
33548	Comfeel Plus Transparent	5 cm x 25 cm	18-08-2016
33536	Comfeel Plus Transparent	9 cm x 14 cm	18-08-2016
33537	Comfeel Plus Transparent	9 cm x 25 cm	18-08-2016

33533	Comfeel Plus Transparent	10 cm x 10 cm	18-08-2016
33517	Comfeel Plus Transparent	13 cm x 13 cm	18-08-2016
33539	Comfeel Plus Transparent	15 cm x 15 cm	18-08-2016
33542	Comfeel Plus Transparent	15 cm x 20 cm	18-08-2016
33518	Comfeel Plus Transparent	18 cm x 18 cm	18-08-2016
33545	Comfeel Plus Transparent	20 cm x 20 cm	18-08-2016
33538	Comfeel Plus Transparent	22.5 cm x 22.5 cm	18-08-2016
33586	Comfeel Plus Transparent, Sacral	17 cm x 17 cm	18-08-2016

Date: **26 NOV 2018** By: 
 Joan Drejer
 Director, Global Regulatory Affairs