

Declaration of Conformity to EU Medical Device Regulation 2017/745

Legal Manufacturer	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN: DK-MF-000025526
EU Product Classification according to Annex VIII	IIb Rule Number: 4
Intended Purpose	The product is intended for moist wound healing and exudate management.
Basic UDI-DI	57089322853077Q
Conformity Assessment Procedure	Annex IX
Notified Body Name and Number	DNV Product Assurance AS - (2460)
Notified Body Certificate Type and Number	EU Quality Management System Certificate - 10000376655-PA-NoMA-DNK
Conformity to Common Specification(s)	No relevant Common Specification to list
Conformity to other Union Legislation(s)	No relevant Union Legislation to list

This EU Declaration of Conformity is applicable for following catalogue numbers:

Catalogue Number	Product Name	Original CE Marking Date yyyy-mm-dd
33533 / 3533	Comfeel Plus Transparent	2016-08-18
33539 / 3539	Comfeel Plus Transparent	2016-08-18
33548 / 3548	Comfeel Plus Transparent	2016-08-18
33545 / 3545	Comfeel Plus Transparent	2016-08-18
335300 / 33530 / 335301 / 3530	Comfeel Plus Transparent	2016-08-18
33542 / 3542	Comfeel Plus Transparent	2016-08-18
33537	Comfeel Plus Transparent	2016-08-18
33536 / 3536	Comfeel Plus Transparent	2016-08-18
33547	Comfeel Plus Transparent	2016-08-18
33517	Comfeel Plus Transparent	2016-08-18
33586	Comfeel Plus Transparent	2016-08-18
33518	Comfeel Plus Transparent	2016-08-18
33538	Comfeel Plus Transparent	2016-08-18

This EU Declaration of Conformity is issued under the sole responsibility of Coloplast A/S. Coloplast A/S declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled.

Date of signature:

2023-07-21

yyyy-mm-dd

Place of signature:

Humblebaek, Denmark

Place, Country

DKBENB, Benedikte Blom, Head of Regulatory Affairs

Signed on behalf of Coloplast A/S:



Name, Title