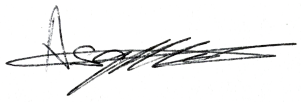
Declaration of Conformity to EU Medical Device Regulation 2017/745

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	57089322852978E
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
3413 / 33413 / 334130 / 3341303	Biatain Non-Adhesive	2008-01-31
3410 / 33410 / 334100 / 3341003	Biatain Non-Adhesive	2008-01-31
3416 / 33416 / 334160 / 3341603	Biatain Non-Adhesive	2008-01-31
6105 / 36105 / 361050 / 3610503	Biatain Non-Adhesive	2008-01-31
3412 / 33412 / 334120 / 3341203	Biatain Non-Adhesive	2008-01-31
3411 / 33411 / 334111	Biatain Non-Adhesive	2008-01-31
33409 / 334091	Biatain Non-Adhesive	2008-01-31
33414 / 334140	Biatain Non-Adhesive	2008-01-31
33417 / 334171	Biatain Non-Adhesive	2008-01-31
33418 / 334180	Biatain Non-Adhesive	2008-01-31
33427 / 334271	Biatain Non-Adhesive	2008-01-31
33428 / 334280	Biatain Non-Adhesive	2008-01-31

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:	2026-08-04
	yyyy-mm-dd
Place of signature:	Humlebaek, Denmark
	Place, Country
	DKADGR, Adam Gregory, Head of Regulatory Affairs, Wound & Skin Care
Signed on behalf of Coloplast A/S:	
	Name, Title