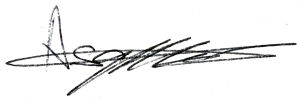
Declaration of Conformity to EU Medical Device Regulation 2017/745

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	57089322853037G
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
33456 / 334560	Biatain Silicone Lite	2022-03-29
33457 / 334570	Biatain Silicone Lite	2022-03-29
33452 / 3345203 / 334520	Biatain Silicone Lite	2015-11-12
33453 / 3345303 / 334531 / 334530	Biatain Silicone Lite	2015-11-12
33446 / 3344633 / 334463	Biatain Silicone Lite	2010-11-23
33445 / 334453 / 3344533	Biatain Silicone Lite	2010-11-23
33444 / 3344433 / 334443	Biatain Silicone Lite	2010-11-23

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:	2024-10-15
	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