Declaration of Conformity to EU Medical Device Regulation 2017/745

Legal Manufacturer	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN:
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	57089322853027E
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
33436 / 334364	Biatain Silicone	2009-11-06
33404	Biatain Silicone	2016-09-07
33400	Biatain Silicone	2016-09-07
33406	Biatain Silicone	2016-09-07
33434 / 334343 / 334345	Biatain Silicone	2009-11-06
33437 / 334373	Biatain Silicone	2009-11-06
33408	Biatain Silicone	2016-09-07
33438 / 334383 / 334384 / 334386	Biatain Silicone	2009-11-06
33400 / 33401	Biatain Silicone	2016-09-07
33435 / 334353 / 334354	Biatain Silicone	2010-06-14
33405	Biatain Silicone	2016-09-07

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:	2022-03-31
	yyyy-mm-dd
Place of signature:	Humlebaek, Denmark
	Place, Country
	DKBENB, Benedikte Blom, Head of Regulatory Affairs
Signed on behalf of Coloplast A/S:	
	Name, Title