

## Declaration of Conformity to EU Medical Device Regulation 2017/745

<b>Legal Manufacturer</b>	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN: DK-MF-000025526
<b>EU Product Classification according to Annex VIII</b>	IIb Rule Number: 4
<b>Intended Purpose</b>	The product is intended for moist wound healing and exudate management of moderate to high exuding wounds, including cavity wounds.
<b>Basic UDI-DI</b>	57089322853147M
<b>Conformity Assessment Procedure</b>	Annex IX
<b>Notified Body Name and Number</b>	DNV Product Assurance AS - (2460)
<b>Notified Body Certificate Type and Number</b>	EU Quality Management System Certificate - 10000376655-PA-NoMA-DNK
<b>Conformity to Common Specification(s)</b>	No relevant Common Specification to list
<b>Conformity to other Union Legislation(s)</b>	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
33502	Biatain Fiber	2019-11-05
33503 / 335030	Biatain Fiber	2019-11-05
33504	Biatain Fiber	2019-11-05
335050 / 33505	Biatain Fiber	2019-11-05
33506 / 335060	Biatain Fiber	2019-11-05
335090 / 33509	Biatain Fiber	2019-11-05
33501 / 335010	Biatain Fiber	2019-11-05
33507 / 335070	Biatain Fiber	2019-11-05
33508 / 335080	Biatain Fiber	2019-11-05


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: 2024-06-12  
yyyy-mm-dd

Place of signature: Humlebaek, Denmark  
Place, Country

DKBERO, Benjamin Rochette, Vice President, Global Regulatory Affairs

Signed on behalf of Coloplast A/S:

A handwritten signature in blue ink, consisting of a large, stylized loop followed by a series of smaller, more intricate strokes.

Name, Title