

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	5708932123537621JL
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
33601 / 336010	Biatain Superabsorber	2024-08-28
33603 / 336030	Biatain Superabsorber	2024-08-28
33605 / 3360503 / 336050	Biatain Superabsorber	2024-08-28
33607 / 3360703	Biatain Superabsorber	2024-08-28
33608 / 336080	Biatain Superabsorber	2024-08-28
33610 / 3361003	Biatain Superabsorber	2024-08-28
3360003 / 33600	Biatain Superabsorber	2024-08-28
33602 / 3360203	Biatain Superabsorber	2024-08-28
33604 / 3360403	Biatain Superabsorber	2024-08-28
336090 / 33609	Biatain Superabsorber	2024-08-28
336060 / 33606	Biatain Superabsorber	2024-08-28

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: 2024-08-28
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