

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

<b>Legal Manufacturer</b>	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN:
<b>EU Product Classification according to Annex VIII</b>	III Rule Number: 14
<b>Intended Purpose</b>	The product is intended for moist wound healing and exudate management of wounds with delayed healing due to bacteria or wounds at risk of infection.
<b>Basic UDI-DI</b>	570893228529386
<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 EU Technical Documentation Assessment Certificate - C545160
<b>Conformity to Common Specification(s)</b>	No relevant Common Specification to list
<b>Conformity to other Union Legislation(s)</b>	Community code relating to medicinal products for human use Directive 2001/83/EC, relevant provisions of Annex 1

This EU Declaration of Conformity is applicable for following catalogue numbers:

Catalogue Number	Product Name	Original CE Marking Date yyyy-mm-dd
9622 / 39622 / 396220 / 3962203	Biatain Ag Non-Adhesive	2008-03-10
9625 / 39625 / 396250 / 3962503	Biatain Ag Non-Adhesive	2008-03-10
5105 / 35105 / 351050 / 3510503	Biatain Ag Non-Adhesive	2008-03-10
9623 / 39623 / 396230 / 3962303	Biatain Ag Non-Adhesive	2008-03-10
9626 / 39626 / 396260 / 3962603	Biatain Ag Non-Adhesive	2008-03-10
3454 / 33454	Biatain Ag Non-Adhesive	2008-04-11
3455 / 33455	Biatain Ag Non-Adhesive	2008-04-11
3567 / 33567 / 335670	Biatain Ag Non-Adhesive	2009-02-03
3569/ 33569 / 335690	Biatain Ag Non-Adhesive	2009-02-03
33448 / 334480	Biatain Ag Non-Adhesive	2009-04-20
33449 / 334490	Biatain Ag Non-Adhesive	2009-04-20

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.

The devices that are covered by the present declaration are in conformity with the relevant Union legislation(s) referenced in this declaration.

Date of signature: 2022-07-01  
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