

## 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>	I Rule Number: 4
<b>Intended Purpose</b>	The ostomy bag is intended to passively collect output from a stoma.
<b>Basic UDI-DI</b>	57089322975228P
<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
12345 / 123450	Assura/Alterna ostomy bag	2001-05-29
12354 / 123540	Assura/Alterna ostomy bag	2001-05-29
12386 / 123860	Assura/Alterna ostomy bag	2001-05-29
12385 / 123850	Assura/Alterna ostomy bag	2001-05-29
46455 / 464559	Assura/Alterna ostomy bag	2001-05-29
12384 / 123840	Assura/Alterna ostomy bag	2001-05-29
12355 / 123550	Assura/Alterna ostomy bag	2001-05-29
12395 / 123950	Assura/Alterna ostomy bag	2001-05-29
12366 / 123660	Assura/Alterna ostomy bag	2001-05-29
46458 / 464589	Assura/Alterna ostomy bag	2001-05-29
12375 / 123750	Assura/Alterna ostomy bag	2001-05-29
46468 / 464689	Assura/Alterna Ostomy bag	2001-05-29
12365 / 123650	Assura/Alterna ostomy bag	2001-05-29
46448 / 464489	Assura/Alterna ostomy bag	2001-05-29
12346 / 123460	Assura/Alterna ostomy bag	2001-05-29
12356 / 123560	Assura/Alterna ostomy bag	2001-05-29
12376 / 123760	Assura/Alterna ostomy bag	2001-05-29
12374 / 123740	Assura/Alterna ostomy bag	2001-05-29
12364 / 123640	Assura/Alterna ostomy bag	2001-05-29
12344	Assura/Alterna ostomy bag	2001-05-29
46465 / 464659	Assura/Alterna ostomy bag	2001-05-29
12394 / 123940	Assura/Alterna ostomy bag	2001-05-29
46445 / 464459	Assura/Alterna ostomy bag	2001-05-29
12396 / 123960	Assura/Alterna ostomy bag	2001-05-29
46444	Assura/Alterna ostomy bag	2001-05-29
46446	Assura/Alterna ostomy bag	2001-05-29
46456	Assura/Alterna ostomy bag	2001-05-29
46457 / 464579	Assura/Alterna ostomy bag	2001-05-29
46447 / 464479	Assura/Alterna ostomy bag	2001-05-29
46467 / 464679	Assura/Alterna ostomy bag	2001-05-29
46469	Assura/Alterna ostomy bag	2001-05-29
46459	Assura/Alterna ostomy bag	2001-05-29

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: 2025-11-07  
yyyy-mm-dd

Place of signature: Humlebaek, Denmark  
Place, Country

DKBENB, Benedikte Blom, Director of Regulatory Affairs, Chronic Care

Signed on behalf of Coloplast A/S:



Name, Title