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	I Rule Number: 4
Intended Purpose	The ostomy bag is intended to passively collect output from a stoma. The adhesive baseplate is attached to the ostomy bag and is intended to adhere to intact skin around the stoma.
Basic UDI-DI	57089322975208K
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
14507	Assura/Alterna ostomy bag	2000-04-25
12175 / 121750	Assura/Alterna ostomy bag	2000-04-25
14504	Assura/Alterna ostomy bag	2000-04-25
12110 / 121100	Assura/Alterna ostomy bag	2000-04-25
12146 / 121460	Assura/Alterna ostomy bag	2000-04-25
12170 / 121700	Assura/Alterna ostomy bag	2000-04-25
12147 / 121470	Assura/Alterna ostomy bag	2000-04-25
14506	Assura/Alterna ostomy bag	2000-04-25
12160 / 121600	Assura/Alterna ostomy bag	2000-04-25
12164 / 121640	Assura/Alterna ostomy bag	2000-04-25
12154 / 121540	Assura/Alterna ostomy bag	2000-04-25
12144 / 121440	Assura/Alterna ostomy bag	2000-04-25
12150 / 121500	Assura/Alterna ostomy bag	2000-04-25
12149	Assura/Alterna ostomy bag	2000-04-25
12145 / 121450	Assura/Alterna ostomy bag	2000-04-25
12156 / 121560	Assura/Alterna ostomy bag	2000-04-25
12134 / 121340	Assura/Alterna ostomy bag	2000-04-25
12140 / 121400	Assura/Alterna ostomy bag	2000-04-25
12120	Assura/Alterna ostomy bag	2000-04-25
46346 / 463469	Assura/Alterna ostomy bag	2000-04-25
14508	Assura/Alterna ostomy bag	2000-04-25

12130 / 121300	Assura/Alterna ostomy bag	2000-04-25
12148	Assura/Alterna ostomy bag	2000-04-25
12155 / 121550	Assura/Alterna ostomy bag	2000-04-25
12136 / 121360	Assura/Alterna ostomy bag	2000-04-25
12177	Assura/Alterna ostomy bag	2000-04-25
12157 / 121570	Assura/Alterna ostomy bag	2000-04-25
12180 / 121800	Assura/Alterna ostomy bag	2000-04-25
12166 / 121660	Assura/Alterna ostomy bag	2000-04-25
14505	Assura/Alterna ostomy bag	2000-04-25
12174 / 121740	Assura/Alterna ostomy bag	2000-04-25
12135 / 121350	Assura/Alterna ostomy bag	2000-04-25
46316 / 463169	Assura/Alterna ostomy bag	2000-04-25
12176 / 121760	Assura/Alterna ostomy bag	2000-04-25
12165 / 121650	Assura/Alterna ostomy bag	2000-04-25
46339	Assura/Alterna ostomy bag	2000-04-25
46336	Assura/Alterna ostomy bag	2000-04-25
46376	Assura/Alterna ostomy bag	2000-04-25
46340	Assura/Alterna ostomy bag	2000-04-25
46360 / 463609	Assura/Alterna ostomy bag	2000-04-25
46351 / 463519	Assura/Alterna ostomy bag	2000-04-25
46356 / 463569	Assura/Alterna ostomy bag	2000-04-25
46320	Assura/Alterna ostomy bag	2000-04-25
12158 / 121580	Assura/Alterna ostomy bag	2000-04-25
46386	Assura/Alterna ostomy bag	2000-04-25
46326 / 463269	Assura/Alterna ostomy bag	2000-04-25
46344	Assura/Alterna ostomy bag	2000-04-25
46341	Assura/Alterna ostomy bag	2000-04-25
46361 / 463619	Assura/Alterna ostomy bag	2000-04-25
46352 / 463529	Assura/Alterna ostomy bag	2000-04-25
46354 / 463549	Assura/Alterna ostomy bag	2000-04-25
46321	Assura/Alterna ostomy bag	2000-04-25
46349 / 463499	Assura/Alterna ostomy bag	2000-04-25
46350 / 463509	Assura/Alterna ostomy bag	2000-04-25
46319	Assura/Alterna ostomy bag	2000-04-25
46342	Assura/Alterna ostomy bag	2000-04-25
46359 / 463599	Assura/Alterna ostomy bag	2000-04-25
46309	Assura/Alterna ostomy bag	2000-04-25
46310	Assura/Alterna ostomy bag	2000-04-25
46311	Assura/Alterna ostomy bag	2000-04-25
46353 / 463539	Assura/Alterna ostomy bag	2000-04-25
46306	Assura/Alterna ostomy bag	2000-04-25
12186	Assura/Alterna ostomy bag	2000-04-25

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
Signed on behalf of Coloplast A/S:	DKBENB, Benedikte Blom, Director of Regulatory Affairs, Chronic Care  Name, Title