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	57089322975118J
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
15051 / 150510	SenSura Ostomy bag	2009-05-20
15303 / 153030	SenSura Ostomy bag	2006-01-06
15304 / 153040	SenSura Ostomy bag	2006-01-06
15043 / 150430	SenSura Ostomy bag	2009-05-20
15307 / 153070	SenSura Ostomy bag	2006-01-06
15041 / 150410	SenSura Ostomy bag	2009-05-20
15040 / 150400	SenSura Ostomy bag	2009-05-20
15308 / 153080	SenSura Ostomy bag	2006-01-06
15313 / 153130	SenSura Ostomy bag	2006-01-06
15315 / 153150	SenSura Ostomy bag	2006-01-06
150420 / 15042	SenSura Ostomy bag	2009-05-20
15314 / 153140	SenSura Ostomy bag	2006-01-06
15306	SenSura Ostomy bag	2006-01-06
15413	SenSura Ostomy bag	2006-01-06
15407	SenSura Ostomy bag	2006-01-06
15405	SenSura Ostomy bag	2006-01-06
15408 / 154081	SenSura Ostomy bag	2006-01-06
15071 / 150710	SenSura Ostomy bag	2009-05-20
15406 / 154061	SenSura Ostomy bag	2006-01-06
15061	SenSura Ostomy bag	2009-05-20
15414	SenSura Ostomy bag	2006-01-06
15403	SenSura Ostomy bag	2006-01-06
15305 / 153050	SenSura Ostomy bag	2006-01-06
15404	SenSura Ostomy bag	2006-01-06
15415	SenSura Ostomy bag	2006-01-06
15401	SenSura Ostomy bag	2006-01-06
15402	SenSura Ostomy bag	2006-01-06

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:	2022-12-13
	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