

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.
Basic UDI-DI	57089322975448Z
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
14897	SenSura Click ostomy bag	2008-11-26
14884	SenSura Click ostomy bag	2007-08-15
14907	SenSura Click ostomy bag	2008-11-26
14894	SenSura Click ostomy bag	2007-08-15
14875	SenSura Click ostomy bag	2007-08-15
14886	SenSura Click ostomy bag	2007-08-15
14906	SenSura Click ostomy bag	2007-08-15
10384 / 103840 / 103849	SenSura Click ostomy bag	2007-08-15
14895 / 148950	SenSura Click ostomy bag	2007-08-15
14874	SenSura Click ostomy bag	2007-08-15
10385 / 103850 / 103859 /	SenSura Click ostomy bag	2007-08-15
14885	SenSura Click ostomy bag	2007-08-15
14905	SenSura Click ostomy bag	2007-08-15
103529 / 10352	SenSura Click ostomy bag	2007-08-15
10374	SenSura Click ostomy bag	2007-08-15
10386 / 103869 / 103860	SenSura Click ostomy bag	2007-08-15
10387 / 103879 / 103870 / 103871	SenSura/Coloplast Click ostomy bag	2007-08-15
14896	SenSura Click ostomy bag	2007-08-15
10351 / 103519	SenSura Click ostomy bag	2007-08-15
10375	SenSura Click ostomy bag	2007-08-15
10376 / 103769	SenSura Click ostomy bag	2007-08-15
11125 / 111250	SenSura Click ostomy bag	2007-08-15

10366 / 103669 / 103660	SenSura Click ostomy bag	2007-08-15
10364 / 103649 / 103640	SenSura Click ostomy bag	2007-08-15
10356 / 103569	SenSura Click ostomy bag	2007-08-15
10365 / 103650 / 103659	SenSura Click ostomy bag	2007-08-15
11126	SenSura Click ostomy bag	2007-08-15
11194 / 111940	SenSura Click ostomy bag	2007-08-15
10355 / 103559	SenSura Click ostomy bag	2007-08-15
10367 / 103671 / 103679 / 103670	SenSura / Coloplast Click ostomy bag	2008-11-26
11186	SenSura Click ostomy bag	2007-08-15
11195 / 111950	SenSura Click ostomy bag	2007-08-15
11197 / 111970	SenSura Click ostomy bag	2008-11-26
11196 / 111960	SenSura Click ostomy bag	2007-08-15
11135	SenSura Click ostomy bag	2007-08-15
10354 / 103549	SenSura Click ostomy bag	2007-08-15
11185	SenSura Click ostomy bag	2007-08-15
11124 / 111240	SenSura Click ostomy bag	2007-08-15
11127 / 111270	SenSura Click ostomy bag	2008-11-26
11114	SenSura Click ostomy bag	2007-08-15
11115	SenSura Click ostomy bag	2007-08-15
11136	SenSura Click ostomy bag	2007-08-15

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: 2023-01-27

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