

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	57089322975138N
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
13397	SenSura Click ostomy bag	2008-11-26
13394	SenSura Click ostomy bag	2007-08-15
13396	SenSura Click ostomy bag	2007-08-15
13324 / 133240	SenSura Click ostomy bag	2007-08-15
13395	SenSura Click ostomy bag	2007-08-15
13316 / 133160	SenSura Click ostomy bag	2007-08-15
13305 / 133050	SenSura Click ostomy bag	2007-08-15
13325 / 133250	SenSura Click ostomy bag	2007-08-15
13314 / 133140	SenSura Click ostomy bag	2007-08-15
13326 / 133260	SenSura Click ostomy bag	2007-08-15
13315 / 133150	SenSura Click ostomy bag	2007-08-15
13304 / 133040	SenSura Click ostomy bag	2007-08-15
13327 / 133270	SenSura Click ostomy bag	2008-11-26
10175	SenSura Click ostomy bag	2007-08-15
10154 / 101541 / 101549 / 101540	SenSura Click ostomy bag	2007-08-15
10166 / 101661 / 101669 / 101660	SenSura Click ostomy bag	2007-08-15
10184 / 101849 / 101840	SenSura Click ostomy bag	2007-08-15
10176	SenSura Click ostomy bag	2007-08-15
10185 / 101859 / 101850	SenSura Click ostomy bag	2007-08-15
10164 / 101641 / 101649 / 101640	SenSura Click ostomy bag	2007-08-15
10156 / 101561 / 101569 / 101560	SenSura Click ostomy bag	2007-08-15
10153	SenSura Click ostomy bag	2007-08-15
10174	SenSura Click ostomy bag	2007-08-15
10165 / 101651 / 101659 / 101650	SenSura Click ostomy bag	2007-08-15
10167 / 101671 / 101679 / 101670	SenSura Click / Coloplast Click ostomy bag	2008-11-26
10186 / 101869 / 101860	SenSura Click ostomy bag	2007-08-15
10187 / 101879 / 101870	SenSura Click ostomy bag	2008-11-26
10155 / 101551 / 101559 / 101550	SenSura Click ostomy bag	2007-08-15
101521 / 101529 / 10152	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:

2025-02-19

yyyy-mm-dd

Place of signature:

Humblebaek, Denmark

Place, Country

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

Signed on behalf of Coloplast A/S:



Name, Title