

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	57089322975058P
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
18371 / 183710	SenSura Mio Ostomy bag	2024-02-09
18373 / 183730	SenSura Mio Ostomy bag	2024-02-09
18370 / 183700	SenSura Mio Ostomy bag	2022-02-25
18372 / 183720	SenSura Mio Ostomy bag	2022-02-25
19714 / 197149	SenSura Mio Ostomy bag	2025-05-27
19715 / 197159	SenSura Mio Ostomy bag	2025-05-27
19716 / 197169	SenSura Mio Ostomy bag	2025-05-27
19717 / 197179	SenSura Mio Ostomy bag	2025-05-27
19718 / 197189	SenSura Mio Ostomy bag	2025-05-27
19719 / 197199	SenSura Mio Ostomy bag	2025-05-27
19720 / 197200	SenSura Mio Ostomy bag	2025-05-27
19721 / 197210	SenSura Mio Ostomy bag	2025-05-27
19722 / 197220	SenSura Mio Ostomy bag	2025-05-27
19723 / 197230	SenSura Mio Ostomy bag	2025-05-27
19724 / 197240	SenSura Mio Ostomy bag	2025-05-27
19725 / 197250	SenSura Mio Ostomy bag	2025-05-27
10635	SenSura Mio Original Ostomy bag	2021-11-15
10634	SenSura Mio Original Ostomy bag	2021-11-15
10621	SenSura Mio Original Ostomy bag	2021-11-15
10685 / 106850	SenSura Mio Ostomy bag	2013-11-28
10683 / 106830	SenSura Mio Ostomy bag	2013-11-28

10670 / 106700	SenSura Mio Ostomy bag	2013-11-28
10622	SenSura Mio Original Ostomy bag	2021-11-15
10674 / 106740	SenSura Mio Ostomy bag	2013-11-28
10684 / 106840	SenSura Mio Ostomy bag	2013-11-28
10673 / 106730	SenSura Mio Ostomy bag	2013-11-28
10671 / 106710	SenSura Mio Ostomy bag	2013-11-28
10691 / 106910	SenSura Mio Ostomy bag	2013-11-28
10672 / 106720	SenSura Mio Ostomy bag	2013-11-28
10624	SenSura Mio Original Ostomy bag	2021-11-15
10681 / 106810	SenSura Mio Ostomy bag	2013-11-28
10633	SenSura Mio Original Ostomy bag	2021-11-15
10631	SenSura Mio Original Ostomy bag	2021-11-15
10623	SenSura Mio Original Ostomy bag	2021-11-15
10611	SenSura Mio Original Ostomy bag	2021-11-15
10884 / 108840 / 108849	SenSura Mio Ostomy bag	2013-11-28
10885 / 108850 / 108859	SenSura Mio Ostomy bag	2013-11-28
10870 / 108700 / 108709	SenSura Mio Ostomy bag	2013-11-28
10872 / 108720 / 108729	SenSura Mio Ostomy bag	2013-11-28
10873 / 108730 / 108739	SenSura Mio Ostomy bag	2013-11-28
10881 / 108810 / 108811 / 108819	SenSura Mio Ostomy bag	2013-11-28
10891 / 108910 / 108911 / 108919	SenSura Mio Ostomy bag	2013-11-28
10883 / 108830 / 108839	SenSura Mio Ostomy bag	2013-11-28
10871 / 108710 / 108719	SenSura Mio Ostomy bag	2013-11-28
10874 / 108740 / 108749	SenSura Mio Ostomy bag	2013-11-28

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: 2025-10-10

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