

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	57089322975098X
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
18121 / 181210	SenSura Mio Concave Ostomy bag	2017-04-27
18100 / 181000	SenSura Mio Concave Ostomy bag	2017-04-27
18131 / 181310	SenSura Mio Concave Ostomy bag	2017-04-27
18101 / 181010	SenSura Mio Concave Ostomy bag	2017-04-27
18110 / 181100	SenSura Mio Concave Ostomy bag	2017-04-27
18130 / 181300	SenSura Mio Concave Ostomy bag	2017-04-27
18120 / 181200	SenSura Mio Concave Ostomy bag	2017-04-27
18123 / 181230	SenSura Mio Concave Ostomy bag	2017-04-27
181220 / 18122	SenSura Mio Concave Ostomy bag	2017-04-27
18132	SenSura Mio Concave Ostomy bag	2017-04-27
181120 / 18112	SenSura Mio Concave Ostomy bag	2017-04-27
18113 / 181130	SenSura Mio Concave Ostomy bag	2017-04-27
18102 / 181020	SenSura Mio Concave Ostomy bag	2017-04-27
18135 / 181350	SenSura Mio Concave Ostomy bag	2017-04-27
18111 / 181110	SenSura Mio Concave Ostomy bag	2017-04-27
18152 / 181520	SenSura Mio Concave Ostomy bag	2017-04-27
18180 / 181800	SenSura Mio Concave Ostomy bag	2017-04-27
18173	SenSura Mio Concave Ostomy bag	2017-04-27
18172 / 181720	SenSura Mio Concave Ostomy bag	2017-04-27
18182	SenSura Mio Concave Ostomy bag	2017-04-27
18163	SenSura Mio Concave Ostomy bag	2017-04-27
18161	SenSura Mio Concave Ostomy bag	2017-04-27
18150	SenSura Mio Concave Ostomy bag	2017-04-27
18162 / 181620	SenSura Mio Concave Ostomy bag	2017-04-27
18160 / 181600	SenSura Mio Concave Ostomy bag	2017-04-27
18171	SenSura Mio Concave Ostomy bag	2017-04-27
18170 / 181700	SenSura Mio Concave Ostomy bag	2017-04-27
18185 / 181850	SenSura Mio Concave Ostomy bag	2017-04-27
18181 / 181810	SenSura Mio Concave Ostomy bag	2017-04-27
18151	SenSura Mio Concave Ostomy bag	2017-04-27

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:

2023-06-08

yyyy-mm-dd

Place of signature:

Humblebaek, Denmark

Place, Country

DKBENB, Benedikte Blom, Head of Regulatory Affairs

Signed on behalf of Coloplast A/S:



Name, Title