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	57089322975068R
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
18386 / 183860	SenSura Mio	2022-02-25
18385	SenSura Mio	2022-02-25
11903	SenSura Mio Flex ostomy bag	2014-01-30
11922	SenSura Mio Flex ostomy bag	2014-01-30
11902	SenSura Mio Flex ostomy bag	2014-01-30
11901	SenSura Mio Flex ostomy bag	2014-01-30
11914	SenSura Mio Flex ostomy bag	2014-01-30
11923	SenSura Mio Flex ostomy bag	2014-01-30
11912	SenSura Mio Flex ostomy bag	2014-01-30
11911	SenSura Mio Flex ostomy bag	2014-01-30
11921 / 119210	SenSura Mio Flex ostomy bag	2014-01-30
11913	SenSura Mio Flex ostomy bag	2014-01-30
122220 / 12222 / 122221 / 122229	SenSura Mio Flex ostomy bag	2014-01-30
122020 / 12202 / 122029	SenSura Mio Flex ostomy bag	2014-01-30
12223 / 122231 / 122239 / 122230	SenSura Mio Flex ostomy bag	2014-01-30
122169 / 122160 / 12216 / 122161	SenSura Mio Flex ostomy bag	2014-01-30
122010 / 12201 / 122019	SenSura Mio Flex ostomy bag	2014-01-30
122139 / 122130 / 12213 / 122131	SenSura Mio Flex ostomy bag	2014-01-30
122120 / 12212 / 122129	SenSura Mio Flex ostomy bag	2014-01-30
12221	SenSura Mio Flex ostomy bag	2014-01-30
12203 / 122030	SenSura Mio Flex ostomy bag	2014-01-30
122110 / 12211 / 122119	SenSura Mio Flex ostomy bag	2014-01-30

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:	2022-12-06
	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