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	57089322975078T
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
11214	SenSura Mio Click ostomy bag	2014-01-30
11222	SenSura Mio Click ostomy bag	2014-01-30
11221	SenSura Mio Click ostomy bag	2014-01-30
11202	SenSura Mio Click ostomy bag	2014-01-30
11213 / 112130	SenSura Mio Click ostomy bag	2014-01-30
11212 / 112120	SenSura Mio Click ostomy bag	2014-01-30
11211 / 112110	SenSura Mio Click ostomy bag	2014-01-30
11201 / 112010	SenSura Mio Click ostomy bag	2014-01-30
11203	SenSura Mio Click ostomy bag	2014-01-30
11223	SenSura Mio Click ostomy bag	2014-01-30
11225	SenSura Mio Click ostomy bag	2014-01-30
11226	SenSura Mio Click ostomy bag	2014-01-30
11402 / 114020 / 114029	SenSura Mio Click ostomy bag	2014-01-30
114250 / 11425 / 114259	SenSura Mio Click ostomy bag	2014-01-30
114260 / 11426 / 114261	SenSura Mio Click ostomy bag	2014-01-30
114010 / 11401	SenSura Mio Click ostomy bag	2014-01-30
114120 / 11412 / 114129	SenSura Mio Click ostomy bag	2014-01-30
114210 / 11421 / 114219	SenSura Mio Click ostomy bag	2014-01-30
11413 / 114131 / 114139 / 114130	SenSura Mio Click ostomy bag	2014-01-30
114220 / 11422 / 114221 / 114229	SenSura Mio Click ostomy bag	2014-01-30
11403 / 114030	SenSura Mio Click ostomy bag	2014-01-30
114230 / 11423 / 114231 / 114239	SenSura Mio Click ostomy bag	2014-01-30
114140 / 11414 / 114141 / 114149	SenSura Mio Click ostomy bag	2014-01-30
11411	SenSura Mio Click 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