

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	57089322975088V
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
13683	SenSura Mio Convex Light convex ostomy bag	2021-09-20
13684	SenSura Mio Convex Soft convex ostomy bag	2021-09-20
13685	SenSura Mio Convex Soft convex ostomy bag	2021-09-20
16526 / 165260	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16527 / 165270	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16511 / 165110	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16531 / 165310	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16554 / 165540	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16541 / 165410	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16552 / 165520	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16510 / 165100	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16547 / 165470	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16521 / 165210	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16543 / 165430	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16534 / 165340	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16546 / 165460	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16551 / 165510	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16512 / 165120	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16522 / 165220	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16501 / 165010	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16530 / 165300	SenSura Mio Convex Light convex ostomy bag	2015-04-28

16523 / 165230	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16533 / 165330	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16513 / 165130	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16505 / 165050	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
165500 / 16550	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16506 / 165060	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16553 / 165530	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16545 / 165450	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16525 / 165250	SenSura Mio Convex Light convex ostomy bag	2015-04-28
165420 / 16542	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
165320 / 16532	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16346	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16335	SenSura Mio Convex Light convex ostomy bag / SenSura Mio Convex Light convex ostomy bag	2015-04-28
16355 / 163550	SenSura Mio Convex Deep convex ostomy bag / SenSura Mio Convex brand logo Deep convex ostomy bag	2015-04-28
16331	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16326 / 16326	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16312	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16301	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16306 / 16306	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16330 / 16330	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16311 / 16311	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16323 / 16323	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16347 / 163470	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16345	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16305 / 163050	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16315	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16343 / 163430	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16310	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16325	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16351 / 163510	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16334	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16313 / 163130	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16352 / 163520	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16322	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16332 / 163320	SenSura Mio Convex Light convex ostomy bag / SenSura Mio Convex Light convex ostomy bag	2015-04-28
16342 / 163420	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16327	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16321	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16341	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16353 / 163530	SenSura Mio Convex Deep convex ostomy bag	2015-04-28

16350	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16354	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16333	SenSura Mio Convex Light convex ostomy bag	2015-04-28

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: 2022-12-14
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