

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
19700	SenSura Mio Convex Soft convex ostomy bag	2025-05-27
19701	SenSura Mio Convex Soft convex ostomy bag	2025-05-27
19702	SenSura Mio Convex Soft convex ostomy bag	2025-05-27
19703	SenSura Mio Convex Soft convex ostomy bag	2025-05-27
19704	SenSura Mio Convex Soft convex ostomy bag	2025-05-27
19705	SenSura Mio Convex Soft convex ostomy bag	2025-05-27
19706	SenSura Mio Convex Soft convex ostomy bag	2025-05-27
19571	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19572	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19573	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19574	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19575	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19576	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19577	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19578	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19579	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19580	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19552	SenSura Mio Convex Deep convex ostomy bag	2025-05-27

19553	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19554	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19555	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19556	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19557	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19558	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19559	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19560	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19564 / 195640	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19565 / 195650	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19566 / 195660	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19567 / 195670	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19568 / 195680	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19569	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19570 / 195700	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19551	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19707 / 197070	SenSura Mio Convex Soft convex ostomy bag	2025-05-27
19708 / 197080	SenSura Mio Convex Soft convex ostomy bag	2025-05-27
19709 / 197090	SenSura Mio Convex Soft convex ostomy bag	2025-05-27
19581 / 195810	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19582 / 195820	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19583 / 195830	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19584 / 195840	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19585 / 195850	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19586 / 195860	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19587 / 195870	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19588 / 195880	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19589 / 195890	SenSura Mio Convex Light convex ostomy bag	2025-05-27
19561 / 195610	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19562 / 195620	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19563 / 195630	SenSura Mio Convex Deep convex ostomy bag	2025-05-27
19710	SenSura Mio Convex Soft convex ostomy bag	2025-05-27
19711	SenSura Mio Convex Soft convex ostomy bag	2025-05-27
19712	SenSura Mio Convex Soft convex ostomy bag	2025-05-27
19713	SenSura Mio Convex Soft convex ostomy bag	2025-05-27
19590	SenSura Mio Convex Light convex ostomy bag	2025-05-27
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
16550 / 165500	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
16542 / 165420	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16532 / 165320	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16346 / 163460	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16335 / 163350	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16355 / 163550	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16331 / 163310	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16326 / 163260	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16312 / 163120	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16301 / 163010	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16306 / 163060	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16330 / 163300	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16311 / 163110	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16323 / 163230	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 / 163150	SenSura Mio Convex Soft convex ostomy bag	2015-04-28
16343 / 163430	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16310 / 163100	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 / 163220	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16332 / 163320	SenSura Mio Convex Light convex ostomy bag	2015-04-28
16342 / 163420	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16327 / 163270	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 / 163500	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16354	SenSura Mio Convex Deep convex ostomy bag	2015-04-28
16333 / 163330	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: 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