

# Declaration of Conformity to EU Medical Device Regulation 2017/745

<b>Legal Manufacturer</b>	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN: DK-MF-000025526
<b>EU Product Classification according to Annex VIII</b>	I Rule Number: 1, 2, 5
<b>Intended Purpose</b>	The Irrigation Set is intended to pass water into the colon, via the stoma, to promote evacuation of output.
<b>Basic UDI-DI</b>	570893295264294TS
<b>Conformity to Common Specification(s)</b>	No relevant Common Specification to list
<b>Conformity to other Union Legislation(s)</b>	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
11750	SenSura Mio Irrigation sleeve	2023-08-17
11751	SenSura Mio Irrigation Set	2023-08-17
11752	Coloplast Irrigation Set	2023-08-17
01003 / 1003	Coloplast Irrigation sleeve	1994-12-15
01110 / 1110	Coloplast/Alterna Irrigation Colotip	2009-07-03
01500	Conseal Irrigation Set	1994-12-15
12820	Assura/Alterna Irrigation Press plate	1997-04-11
128300 / 12830	Assura/Alterna Irrigation Set	2001-05-29
128340 / 12834	Assura/Alterna Irrigation Sleeves	1997-04-11
128350 / 12835	Assura/Alterna Irrigation Sleeves	1997-04-11
128360 / 12836	Assura/Alterna Irrigation Sleeves	1997-04-11
01511 / 1511	Coloplast/Alterna Irrigation Water bag	2009-07-03
015010 / 01501 / 1501 / 0150	Coloplast Irrigation Set	1994-12-15
01510 / 015102	Coloplast Irrigation Set	1994-12-15
12833	Assura/Alterna Irrigation Set	2001-05-29

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: 2023-08-17

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