

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: 1, 2, 5
Intended Purpose	The Irrigation Set is intended to pass water into the colon, via the stoma, to promote evacuation of output.
Basic UDI-DI	570893295264294TS
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
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