

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 product is intended to promote evacuation of the contents in the lower and descending colon.
Basic UDI-DI	5708932117304282HM
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
29152	Peristeen Plus Transanal Irrigation	2021-01-22
29140 / 291400	Peristeen Plus Transanal Irrigation	2021-01-22
29141 / 291410	Peristeen Plus Transanal Irrigation	2021-01-22
29142 / 291420	Peristeen Plus Transanal Irrigation	2021-01-22
29143 / 291431 / 291432	Peristeen Plus Transanal Irrigation	2021-01-22
29144 / 291441 / 291440	Peristeen Plus Transanal Irrigation	2021-01-22
29145 / 291450	Peristeen Plus Transanal Irrigation	2021-01-22
29146 / 291461 / 291460	Peristeen Plus Transanal Irrigation	2021-01-22
29147 / 291470	Peristeen Plus Transanal Irrigation	2021-01-22
29148 / 291480	Peristeen Plus Transanal Irrigation	2021-01-22
29149 / 291490	Peristeen Plus Transanal Irrigation	2021-01-22
29150 / 291501 / 291502	Peristeen Plus Transanal Irrigation	2021-01-22
29151	Peristeen Plus Transanal Irrigation	2021-01-22
29165 / 291650	Peristeen Plus Transanal Irrigation	2023-12-21

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:

2024-09-19

yyyy-mm-dd

Place of signature:

Humblebaek, Denmark

Place, Country

DKBENB, Benedikte Blom, Director of Regulatory Affairs, Chronic Care

Signed on behalf of Coloplast A/S:



Name, Title