

Declaration of Conformity to EU Medical Device Regulation 2017/745

Legal Manufacturer	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN:
Product Name	Coloplast Urostomy night bag
EU Product Classification according to Annex VIII	I Rule Number: 1
Intended Purpose	The urine bag is intended to passively collect urine.
Basic UDI-DI	5708932117220702H3
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
21365 / 213650	Coloplast Urostomy night bag	2001-12-14

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: 2021-05-17

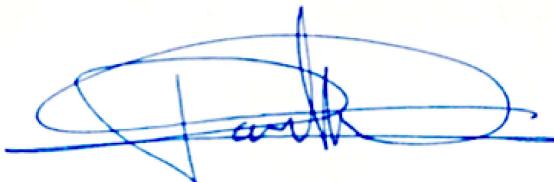
yyyy-mm-dd

Place of signature: Humlebaek, Denmark

Place, Country

DKBERO, Benjamin Rochette, Vice President, Global Regulatory Affairs

Signed on behalf of Coloplast A/S:



Name, Title