

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

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

<b>Catalogue Number</b>	<b>Product Name</b>	<b>Original CE Marking Date yyyy-mm-dd</b>
21365 / 213650	Coloplast Urostomy night bag	2001-12-14

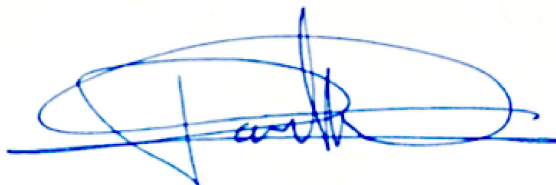
This EU Declaration of Conformity is issued under the sole responsibility of Coloplast A/S. Coloplast A/S declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and 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