

## 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
<b>Intended Purpose</b>	The urine bag is intended to passively collect urine.
<b>Basic UDI-DI</b>	57089322978729M
<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>
5166 / 051661 / 05166 / 051660	Conveen Security+ Urine collection bag	2001-03-13
5160 / 51602 / 05160 / 051600 / 051601	Conveen Security+ Urine collection bag	2001-03-13
5167 / 51674 / 05167 / 051671 / 051670	Conveen Security+ Urine collection bag	2001-03-13
21022 / 210220	Conveen Security+ Urine collection bag	2001-03-13
5161 / 51612 / 05161 / 051610 / 051611	Conveen Security+ Urine collection bag	2001-03-13
5164 / 05164 / 051641 / 051640	Conveen Security+ Urine collection bag	2001-03-13
5165 / 51654 / 05165 / 051651 / 051650	Conveen Security+ Urine collection bag	2001-03-13
21026	Conveen Security+ Urine collection bag	2013-05-23
21027	Conveen Security+ Urine collection bag	2013-03-23
21061	Conveen Security+ Urine collection bag.	2001-03-13
21086 / 210860	Conveen Security+ Urine collection bag	2009-07-30
21042 / 210420	Conveen Security+ Urine collection bag	2005-01-27

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: 2025-10-10  
yyyy-mm-dd

Place of signature: Humlebaek, Denmark  
Place, Country

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

Signed on behalf of Coloplast A/S:



Name, Title