Declaration of Conformity to EU Medical Device Regulation 2017/745

Legal Manufacturer	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN:
Product Name	Conveen Security+ Urine collection 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	57089322978729M
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
5166 / 05166 / 051660 / 051661	Conveen Security+ Urine collection bag	2001-03-13
05160 / 051600 / 5160	Conveen Security+ Urine collection bag	2001-03-13
051670 / 5167 / 05167 / 051671 / 51674	Conveen Security+ Urine collection bag	2001-03-13
21022	Conveen Security+ Urine collection bag	2001-03-13
05161 / 051610 / 5161 / 51612 / 051611	Conveen Security+ Urine collection bag	2001-03-13
05164 / 051640 / 051641 / 5164	Conveen Security+ Urine collection bag	2001-03-13
05165 / 051650 / 5165 / 051651	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:	2021-05-12
	yyyy-mm-dd
Place of signature:	Humlebaek, Denmark
	Place, Country
Signed on behalf of Coloplast A/S:	DKBERO, Benjamin Rochette, Vice President, Global Regulatory Affairs
	
	Name, Title