Declaration of Conformity to EU Medical Device Regulation 2017/745

Legal Manufacturer	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN:
Product Name	Conveen Urisheath/Uriliner
EU Product Classification according to Annex VIII	I Rule Number: 1
Intended Purpose	Urisheaths are intended to drain urine, normally into a urinary collection bag.
Basic UDI-DI	57089322978479N
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
5100 / 05100 / 051001	Conveen® Sheath Liner	1996-03-21
051250 / 05125 / 5125 / 51250	Conveen Urisheath/Uriliner	1999-10-29
5120 / 051200 / 05120 / 51200	Conveen Urisheath/Uriliner	1999-10-29
05135 / 5135 / 051350 / 51350	Conveen Urisheath/Uriliner	1999-10-29
5140 / 05140 / 051400 / 51400	Conveen Urisheath/Uriliner	1999-10-29
5130 / 05130 / 051300 / 51300	Conveen Urisheath/Uriliner	1999-10-29

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
Signed on behalf of Coloplast A/S:	DKBERO, Benjamin Rochette, Vice President, Global Regulatory Affairs
	
	Name, Title