Declaration of Conformity to EU Medical Device Regulation 2017/745

Legal Manufacturer	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN: DK-MF-000025526
EU Product Classification according to Annex VIII	Is Rule Number: 5
Intended Purpose	The product is intended for intermittent catheterisation through the urethra.
Basic UDI-DI	57089322978339B
Conformity Assessment Procedure	Annex IX
Notified Body Name and Number	DNV Product Assurance AS - (2460)
Notified Body Certificate Type and Number	EU Quality Management System Certificate - 10000376655-PA-NoMA-DNK
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
28578 / 285780 / 285789	SpeediCath Compact	2005-05-30
28580 / 285800 / 285809	SpeediCath Compact	2003-11-12
28582 / 285820 / 285829	SpeediCath Compact	2003-11-12
28584 / 285840 / 285849	SpeediCath Compact	2003-11-12
28810 / 288100 / 288109	SpeediCath Compact Plus	2009-10-14
28812 / 288120 / 288129	SpeediCath Compact Plus	2009-10-14
28814 / 288140 / 288149	SpeediCath Compact Plus	2009-10-14
28576 / 285760 / 285769	SpeediCath Compact	2009-01-30

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:	2024-10-23 yyyy-mm-dd
Place of signature:	Humlebaek, Denmark Place, Country
Signed on behalf of Coloplast A/S:	DKBENB, Benedikte Blom, Director of Regulatory Affairs, Chronic Care  Name, Title