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 or a continent urinary stoma. The product may also be used for intermittent dilation of the urethra.
Basic UDI-DI	57089322978269E
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
28408 / 284081	SpeediCath Standard	2000-02-16
28410 / 284101	SpeediCath Standard	2000-02-16
28412 / 284121 / 284120	SpeediCath Standard	2000-02-16
28414 / 284141 / 284140	SpeediCath Standard	2000-02-16
28416 / 284160	SpeediCath Standard	2000-02-16
284180 / 28418	SpeediCath Standard	2000-02-16
28490 / 284900	SpeediCath Standard	2000-02-16
28492 / 284920	SpeediCath Standard	2000-02-16
28494 / 284940	SpeediCath Standard	2000-02-16
28496	SpeediCath Standard	2013-10-28
28506 / 285060	SpeediCath Standard	2000-02-16
28508 / 285080 / 285081	SpeediCath Standard	2000-02-16
28510 / 285100 / 285101	SpeediCath Standard	2000-02-16
28512 / 285120 / 285121	SpeediCath Standard	2000-02-16
28514 / 285140 / 285141	SpeediCath Standard	2000-02-16
28516 / 285160	SpeediCath Standard	2000-02-16
28606 / 286060	SpeediCath Standard	2000-02-16
28608 / 286080	SpeediCath Standard	2000-02-16

28610 / 286100	SpeediCath Standard	2000-02-16
28612 / 286120	SpeediCath Standard	2000-02-16
28706 / 287060 / 287061	SpeediCath Standard	2000-02-16
287080 / 28708 / 287081	SpeediCath Standard	2000-02-16
287100 / 28710 / 287101 / 29016	SpeediCath Standard	2000-02-16
27496	SpeediCath Standard	2013-10-28
27412 / 274120	SpeediCath Standard	2012-04-17
27416 / 274160	SpeediCath Standard	2012-04-17
275140 / 27514	SpeediCath Standard	2012-04-17
27408 / 274080	SpeediCath Standard	2012-04-17
27490 / 274900	SpeediCath Standard	2012-04-17
27418 / 274180	SpeediCath Standard	2012-04-17
274100 / 27410	SpeediCath Standard	2012-04-17
275100 / 27510	SpeediCath Standard	2012-04-17
27612 / 276120	SpeediCath Standard	2012-04-17
27710 / 277100	SpeediCath Standard	2012-04-17
27494 / 274940	SpeediCath Standard	2012-04-17
274140 / 27414	SpeediCath Standard	2012-04-17
275080 / 27508	SpeediCath Standard	2012-04-17
27516 / 275160	SpeediCath Standard	2012-04-17
27708 / 277080	SpeediCath Standard	2012-04-17
275120 / 27512	SpeediCath Standard	2012-04-17
27610 / 276100	SpeediCath Standard	2012-04-17
27706 / 277060	SpeediCath Standard	2012-04-17
27608 / 276080	SpeediCath Standard	2012-04-17
27492 / 274920	SpeediCath Standard	2012-04-17

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:	2023-06-08
	yyyy-mm-dd
Place of signature:	Humlebaek, Denmark
	Place, Country
	DKBENB, Benedikte Blom, Head of Regulatory Affairs
Signed on behalf of Coloplast A/S:	
	Name, Title