



EC Declaration of Conformity to Council Directive 93/42/EEC and amendments concerning Medical Devices

Manufacturer	Coloplast A/S Holtedam 1 3050 Humlebaek Denmark
Product	Product family: Urinary Catheters for Intermittent Use (sterile)
	Product name: SpeediCath/SpeediCath Standard/SpeediCath Flex/SpeediCath Navi, SpeediCath Soft/SpeediCath Flex Set
Description	On primary packaging: See attachment
	Global Medical Device Nomenclature code/name: 45603 Single-administration urethral drainage catheter 45605 Single-administration urethral catheterization kit, self- applied, single-use
EC Product Class according to Annex IX	Class: Sterile class I Rule no.: 5
Notified Body	DNV GL Presafe AS (2460) Veritasveien 3, N-1363 Høvik, Norway
ID no.	258

The undersigned, Director, RA Innovation and Market Expansion, declares that the following devices:
SpeediCath/SpeediCath Standard/SpeediCath Flex/SpeediCath Navi, SpeediCath Soft/SpeediCath Flex Set
conform to the relevant provisions of the European Communities' Council Directive 93/42/EEC and
amendments and are in accordance with:

Annex II Conformity Assessment Procedure (full quality assurance system) as verified by the
DNV GL Presafe AS (2460).

This product was originally CE-marked: 16/02/2000

Date: **22 APR 2021**

By: 

Lykke Forchhammer
Director, RA Innovation and Market Expansion

Description on Primary Packaging for

Product family:

Urinary Catheters for Intermittent Use (sterile)

Product name:

SpeediCath/SpeediCath Standard/SpeediCath Flex/SpeediCath Navi, SpeediCath Soft/SpeediCath Flex Set

Item number	Product name	Product description	Date of the original CE-marking
28408	SpeediCath/SpeediCath Standard	Male, CH8	16-02-2000
28410	SpeediCath/SpeediCath Standard	Male, CH10	16-02-2000
28412	SpeediCath/SpeediCath Standard	Male, CH 12	16-02-2000
28414	SpeediCath/SpeediCath Standard	Male, CH 14	16-02-2000
28416	SpeediCath/SpeediCath Standard	Male, CH 16	16-02-2000
28418	SpeediCath/SpeediCath Standard	Male, CH 18	16-02-2000
28490	SpeediCath/SpeediCath Standard	Tiemann, CH 10	16-02-2000
28492	SpeediCath/SpeediCath Standard	Tiemann, CH 12	16-02-2000
28494	SpeediCath/SpeediCath Standard	Tiemann, CH 14	16-02-2000
28496	SpeediCath/SpeediCath Standard	Tiemann, CH 16	28-10-2013
28506	SpeediCath/SpeediCath Standard	Female, CH 6	16-02-2000
28508	SpeediCath/SpeediCath Standard	Female, CH 8	16-02-2000
28510	SpeediCath/SpeediCath Standard	Female, CH 10	16-02-2000
28512	SpeediCath/SpeediCath Standard	Female, CH 12	16-02-2000
28514	SpeediCath/SpeediCath Standard	Female, CH 14	16-02-2000
28516	SpeediCath/SpeediCath Standard	Female, CH 16	16-02-2000
28606	SpeediCath/SpeediCath Standard	Boy, CH 6	16-02-2000
28608	SpeediCath/SpeediCath Standard	Boy, CH 8	16-02-2000
28610	SpeediCath/SpeediCath Standard	Boy, CH 10	16-02-2000
28612	SpeediCath/SpeediCath Standard	Boy, CH 12	16-02-2000
28706	SpeediCath/SpeediCath Standard	Paediatric, CH 6	16-02-2000
28708	SpeediCath/SpeediCath Standard	Paediatric, CH 8	16-02-2000
28710	SpeediCath/SpeediCath Standard	Paediatric, CH 10	16-02-2000

28481	SpeediCath/SpeediCath Standard w. accessories	Male, CH8	17-05-2005
28482	SpeediCath/SpeediCath Standard w. accessories	Male, CH10	17-05-2005
28483	SpeediCath/SpeediCath Standard w. accessories	Male, CH12	17-05-2005
28484	SpeediCath/SpeediCath Standard w. accessories	Male, CH14	17-05-2005
28485	SpeediCath/SpeediCath Standard w. accessories	Male, CH16	17-05-2005
28486	SpeediCath/SpeediCath Standard w. accessories	Male, CH18	17-05-2005
28499	SpeediCath/SpeediCath Standard w. accessories	Female, CH6	17-05-2005
28500	SpeediCath/SpeediCath Standard w. accessories	Female, CH8	17-05-2005
28501	SpeediCath/SpeediCath Standard w. accessories	Female, CH10	17-05-2005
28502	SpeediCath/SpeediCath Standard w. accessories	Female, CH12	17-05-2005
28503	SpeediCath/SpeediCath Standard w. accessories	Female, CH14	17-05-2005
28504	SpeediCath/SpeediCath Standard w. accessories	Female, CH16	17-05-2005
27706	SpeediCath/SpeediCath Standard	Paediatric, CH 6	17-04-2012
27708	SpeediCath/SpeediCath Standard	Paediatric, CH 8	17-04-2012
27710	SpeediCath/SpeediCath Standard	Paediatric, CH 10	17-04-2012
27608	SpeediCath/SpeediCath Standard	Boy, CH 8	17-04-2012
27610	SpeediCath/SpeediCath Standard	Boy, CH 10	17-04-2012
27612	SpeediCath/SpeediCath Standard	Boy, CH 12	17-04-2012
27508	SpeediCath/SpeediCath Standard	Female, CH 8	17-04-2012
27510	SpeediCath/SpeediCath Standard	Female, CH 10	17-04-2012
27512	SpeediCath/SpeediCath Standard	Female, CH 12	17-04-2012
27514	SpeediCath/SpeediCath Standard	Female, CH 14	17-04-2012
27516	SpeediCath/SpeediCath Standard	Female, CH 16	17-04-2012
27408	SpeediCath/SpeediCath Standard	Male, CH 8	17-04-2012
27410	SpeediCath/SpeediCath Standard	Male, CH 10	17-04-2012
27412	SpeediCath/SpeediCath Standard	Male, CH 12	17-04-2012
27414	SpeediCath/SpeediCath Standard	Male, CH 14	17-04-2012
27416	SpeediCath/SpeediCath Standard	Male, CH 16	17-04-2012
27418	SpeediCath/SpeediCath Standard	Male, CH 18	17-04-2012

27490	SpeediCath/SpeediCath Standard	Tiemann, CH 10	17-04-2012
27492	SpeediCath/SpeediCath Standard	Tiemann, CH 12	17-04-2012
27494	SpeediCath/SpeediCath Standard	Tiemann, CH 14	17-04-2012
27496	SpeediCath/SpeediCath Standard	Tiemann, CH 16	28-10-2013
28910	SpeediCath Flex	Pocket size, Male, CH 10	13-05-2016
28912	SpeediCath Flex	Pocket size, Male, CH 12	13-05-2016
28914	SpeediCath Flex	Pocket size, Male, CH 14	13-05-2016
28916	SpeediCath Flex	Male, CH 16	13-05-2016
28920	SpeediCath Flex	Male, CH 10	13-05-2016
28922	SpeediCath Flex	Male, CH 12	13-05-2016
28924	SpeediCath Flex	Male, CH 14	13-05-2016
29010	SpeediCath Navi	Male, CH 10	09-01-2019
29012	SpeediCath Navi	Male, CH 12	09-01-2019
29014	SpeediCath Navi	Male, CH 14	09-01-2019
29016	SpeediCath Navi	Male, CH 16	09-01-2019
29021	SpeediCath Navi	Boy, CH 10	06-08-2019
29022	SpeediCath Navi	Boy, CH 12	06-08-2019
27010	SpeediCath Soft	Male, CH10	15-01-2020
27012	SpeediCath Soft	Male, CH12	15-01-2020
27014	SpeediCath Soft	Male, CH14	15-01-2020
27016	SpeediCath Soft	Male, CH16	15-01-2020
28931	SpeediCath Flex Set	Male CH10	22-04-2021
28932	SpeediCath Flex Set	Male CH12	22-04-2021
28934	SpeediCath Flex Set	Male CH14	22-04-2021
28936	SpeediCath Flex Set	Male CH16	22-04-2021

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