



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 Indwelling Catheters
	Product name: FOLYSIL® Foley Catheter for Neobladder
Description	On primary packaging: See attachment
	Global Medical Device Nomenclature code/name: 32331 Indwelling urethral drainage/irrigation catheter
EC Product Class according to Annex IX	Class: Sterile class IIb Rule no.: 5
Notified Body	Presafe Denmark A/S - (0543) Tuborg Parkvej 8, DK-2900 Hellerup, Denmark
ID no.	181

The undersigned, Head of Regulatory Affairs, declares that the following devices:
FOLYSIL® Foley Catheter for Neobladder
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 Presafe Denmark A/S - (0543).

This product was originally CE-marked: 15/01/1998

Date: 02/12/2016 By: 
Sihem Darraji
Head of Regulatory Affairs

Description on Primary Packaging for

Product family:

Urinary Indwelling Catheters

Product name:

FOLYSIL® Foley Catheter for Neobladder

Item number	Product name	Product description	Date of the original CE-marking
AA6820	FOLYSIL® FOLEY CATHETER / FOR NEO-BLADDER / 3-WAY / SILICONE	FOLYSIL® Foley catheter for neobladder silicone CH FR 20	15/01/1998
AA6822	FOLYSIL® FOLEY CATHETER / FOR NEO-BLADDER / 3-WAY / SILICONE	FOLYSIL® Foley catheter for neobladder silicone CH FR 22	15/01/1998
AA6918	FOLYSIL® FOLEY CATHETER / FOR NEO-BLADDER / WITH EYE UNDER BALLOON / 3-WAY / SILICONE	FOLYSIL® Foley catheter for neobladder with eye under balloon silicone CH FR 18	07/09/2000
AA6920	FOLYSIL® FOLEY CATHETER / FOR NEO-BLADDER / WITH EYE UNDER BALLOON / 3-WAY / SILICONE	FOLYSIL® Foley catheter for neobladder with eye under balloon silicone CH FR 20	07/09/2000
AA6922	FOLYSIL® FOLEY CATHETER / FOR NEO-BLADDER / WITH EYE UNDER BALLOON / 3-WAY / SILICONE	FOLYSIL® Foley catheter for neobladder with eye under balloon silicone CH FR 22	07/09/2000

Date: 02/12/2016 By: 
 Sihem Darraji
 Head of Regulatory Affairs