



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® Catheter
Description	On primary packaging: See attachment
	Global Medical Device Nomenclature code/name: 34917 Indwelling urethral drainage 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.	180

The undersigned, Director of Global Regulatory Affairs, Coloplast Interventional Urology, declares that the following devices:

FOLYSIL® Catheter

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: 10/10/2019

By: 

Sihem Darraji

Director of Global Regulatory Affairs, Coloplast Interventional Urology



Description on Primary Packaging for

Product family:

Urinary Indwelling Catheters

Product name:

FOLYSIL® Catheter

Item number	Product name	Product description	Date of the original CE-marking
AA6106	FOLYSIL® NELATON / Silicone Foley catheter 2-way / Pediatric	FOLYSIL® catheter pediatric with introducer straight CH FR 06, silicone, 2-way	20/12/1999
AA6108	FOLYSIL® NELATON / Silicone Foley catheter 2-way / Pediatric	FOLYSIL® catheter pediatric with introducer straight CH FR 08, silicone, 2-way	20/12/1999
AA6110	FOLYSIL® NELATON / Silicone Foley catheter 2-way / Pediatric	FOLYSIL® catheter pediatric with introducer straight CH FR 10, silicone, 2-way	20/12/1999
AA6112	FOLYSIL® NELATON / Silicone Foley catheter 2-way	FOLYSIL® catheter straight CH FR 12, silicone, 2-way	15/01/1998
AA6114	FOLYSIL® NELATON / Silicone Foley catheter 2-way	FOLYSIL® catheter straight CH FR 14, silicone, 2-way	15/01/1998
AA6116	FOLYSIL® NELATON / Silicone Foley catheter 2-way	FOLYSIL® catheter straight CH FR 16, silicone, 2-way	15/01/1998
AA6118	FOLYSIL® NELATON / Silicone Foley catheter 2-way	FOLYSIL® catheter straight CH FR 18, silicone, 2-way	15/01/1998
AA6120	FOLYSIL® NELATON / Silicone Foley catheter 2-way	FOLYSIL® catheter straight CH FR 20, silicone, 2-way	15/01/1998
AA6122	FOLYSIL® NELATON / Silicone Foley catheter 2-way	FOLYSIL® catheter straight CH FR 22, silicone, 2-way	15/01/1998
AA6124	FOLYSIL® NELATON / Silicone Foley catheter 2-way	FOLYSIL® catheter straight CH FR 24, silicone, 2-way	15/01/1998
AA6308	FOLYSIL® TIEMANN / Silicone Foley catheter 2-way / Pediatric	FOLYSIL® catheter pediatric with introducer Tiemann CH FR 08, silicone, 2-way	15/01/1998
AA6310	FOLYSIL® TIEMANN / Silicone Foley catheter 2-way / Pediatric	FOLYSIL® catheter pediatric with introducer Tiemann CH FR 10, silicone, 2-way	15/01/1998
AA6312	FOLYSIL® TIEMANN / Silicone Foley catheter 2-way	FOLYSIL® catheter Tiemann CH FR 12, silicone, 2-way	15/01/1998
AA6314	FOLYSIL® TIEMANN / Silicone Foley		15/01/1998

	catheter 2-way	FOLYSIL® catheter Tiemann CH FR 14, silicone, 2-way	
AA6316	FOLYSIL® TIEMANN / Silicone Foley catheter 2-way	FOLYSIL® catheter Tiemann CH FR 16, silicone, 2-way	15/01/1998
AA6318	FOLYSIL® TIEMANN / Silicone Foley catheter 2-way	FOLYSIL® catheter Tiemann CH FR 18, silicone, 2-way	15/01/1998
AA6320	FOLYSIL® TIEMANN / Silicone Foley catheter 2-way	FOLYSIL® catheter Tiemann CH FR 20, silicone, 2-way	15/01/1998
AA6322	FOLYSIL® TIEMANN / Silicone Foley catheter 2-way	FOLYSIL® catheter Tiemann CH FR 22, silicone, 2-way	15/01/1998
AA6324	FOLYSIL® TIEMANN / Silicone Foley catheter 2-way	FOLYSIL® catheter Tiemann CH FR 24, silicone, 2-way	15/01/1998
AA6406	FOLYSIL® Foley catheter / over the guide / 2-way / silicone / Pediatric	FOLYSIL® catheter pediatric over the guide CH FR 06, silicone, 2-way	15/01/1998
AA6408	FOLYSIL® Foley catheter / over the guide / 2-way / silicone / Pediatric	FOLYSIL® catheter pediatric over the guide CH FR 08, silicone, 2-way	15/01/1998
AA6410	FOLYSIL® Foley catheter / over the guide / 2-way / silicone / Pediatric	FOLYSIL® catheter pediatric over the guide CH FR 10, silicone, 2-way	15/01/1998
AA6412	FOLYSIL® Foley catheter / over the guide / 2-way / silicone	FOLYSIL® catheter over the guide CH FR 12, silicone, 2- way	15/01/1998
AA6414	FOLYSIL® Foley catheter / over the guide / 2-way / silicone	FOLYSIL® catheter over the guide CH FR 14, silicone, 2- way	15/01/1998
AA6416	FOLYSIL® Foley catheter / over the guide / 2-way / silicone	FOLYSIL® catheter over the guide CH FR 16, silicone, 2- way	15/01/1998
AA6418	FOLYSIL® Foley catheter / over the guide / 2-way / silicone	FOLYSIL® catheter over the guide CH FR 18, silicone, 2- way	15/01/1998
AA6420	FOLYSIL® Foley catheter / over the guide / 2-way / silicone	FOLYSIL® catheter over the guide CH FR 20, silicone, 2- way	15/01/1998
AA6422	FOLYSIL® Foley catheter / over the guide / 2-way / silicone	FOLYSIL® catheter over the guide CH FR 22, silicone, 2- way	15/01/1998
AA6424	FOLYSIL® Foley catheter / over the guide / 2-way / silicone	FOLYSIL® catheter over the guide CH FR 24, silicone, 2- way	15/01/1998
AA6512	FOLYSIL® Foley catheter / female / 2- way / silicone	FOLYSIL® catheter female straight CH FR 12, silicone, 2-way	15/01/1998
AA6514	FOLYSIL® Foley catheter / female / 2- way / silicone	FOLYSIL® catheter female straight CH FR 14, silicone, 2-way	15/01/1998

AA6516	FOLYSIL® Foley catheter / female / 2-way / silicone	FOLYSIL® catheter female straight CH FR 16, silicone, 2-way	15/01/1998
AA6518	FOLYSIL® Foley catheter / female / 2-way / silicone	FOLYSIL® catheter female straight CH FR 18, silicone, 2-way	15/01/1998
AA6520	FOLYSIL® Foley catheter / female / 2-way / silicone	FOLYSIL® catheter female straight CH FR 20, silicone, 2-way	15/01/1998
AA6522	FOLYSIL® Foley catheter / female / 2-way / silicone	FOLYSIL® catheter female straight CH FR 22, silicone, 2-way	15/01/1998
AA6524	FOLYSIL® Foley catheter / female / 2-way / silicone	FOLYSIL® catheter female straight CH FR 24, silicone, 2-way	15/01/1998
AA6612	FOLYSIL® Foley catheter / grooved / 2-way / silicone	FOLYSIL® catheter grooved CH FR 12, silicone, 2-way	15/01/1998
AA6614	FOLYSIL® Foley catheter / grooved / 2-way / silicone	FOLYSIL® catheter grooved CH FR 14, silicone, 2-way	15/01/1998
AA6616	FOLYSIL® Foley catheter / grooved / 2-way / silicone	FOLYSIL® catheter grooved CH FR 16, silicone, 2-way	15/01/1998
AA6618	FOLYSIL® Foley catheter / grooved / 2-way / silicone	FOLYSIL® catheter grooved CH FR 18, silicone, 2-way	15/01/1998
AA6620	FOLYSIL® Foley catheter / grooved / 2-way / silicone	FOLYSIL® catheter grooved CH FR 20, silicone, 2-way	15/01/1998
AA6622	FOLYSIL® Foley catheter / grooved / 2-way / silicone	FOLYSIL® catheter grooved CH FR 22, silicone, 2-way	15/01/1998
AA6624	FOLYSIL® Foley catheter / grooved / 2-way / silicone	FOLYSIL® catheter grooved CH FR 24, silicone, 2-way	15/01/1998
AA6C18	FOLYSIL® NELATON / Silicone Foley catheter 2-way	FOLYSIL® catheter straight CH FR 18, silicone, 2-way	15/01/1998
AA6C20	FOLYSIL® NELATON / Silicone Foley catheter 2-way	FOLYSIL® catheter straight CH FR 20, silicone, 2-way	15/01/1998
AA6C22	FOLYSIL® NELATON / Silicone Foley catheter 2-way	FOLYSIL® catheter straight CH FR 22, silicone, 2-way	15/01/1998
AA6C24	FOLYSIL® NELATON / Silicone Foley catheter 2-way	FOLYSIL® catheter straight CH FR 24, silicone, 2-way	15/01/1998
AA9312	FOLYSIL® TIEMANN + / Silicone Foley catheter 2-way	FOLYSIL® catheter Tiemann+ CH FR 12, silicone, 2-way	01/10/2004
AA9314	FOLYSIL® TIEMANN + / Silicone Foley catheter 2-way	FOLYSIL® catheter Tiemann+ CH FR 14, silicone, 2-way	01/10/2004
AA9316	FOLYSIL® TIEMANN + / Silicone Foley catheter 2-way	FOLYSIL® catheter Tiemann+ CH FR 16, silicone, 2-way	01/10/2004
AA9318	FOLYSIL® TIEMANN + / Silicone Foley catheter 2-way	FOLYSIL® catheter Tiemann+ CH FR 18, silicone, 2-way	01/10/2004
AA9320	FOLYSIL® TIEMANN + / Silicone Foley catheter 2-way	FOLYSIL® catheter Tiemann+ CH FR 20, silicone, 2-way	01/10/2004
AA9322	FOLYSIL® TIEMANN + / Silicone Foley		01/10/2004

	catheter 2-way	FOLYSIL® catheter Tiemann+ CH FR 22, silicone, 2-way	
AA9324	FOLYSIL® TIEMANN + / Silicone Foley catheter 2-way	FOLYSIL® catheter Tiemann+ CH FR 24, silicone, 2-way	01/10/2004
HA6106	FOLYSIL® Foley catheter straight	FOLYSIL® catheter pediatric with introducer straight CH FR 06, silicone, 2-way	20/12/1999
HA6108	FOLYSIL® Foley catheter straight	FOLYSIL® catheter pediatric with introducer straight CH FR 08, silicone, 2-way	20/12/1999
HA6110	FOLYSIL® Foley catheter straight	FOLYSIL® catheter pediatric with introducer straight CH FR 10, silicone, 2-way	20/12/1999
HA6112	FOLYSIL® Foley catheter straight	FOLYSIL® catheter straight CH FR 12, silicone, 2-way	15/01/1998
HA6114	FOLYSIL® Foley catheter straight	FOLYSIL® catheter straight CH FR 14, silicone, 2-way	15/01/1998
HA6116	FOLYSIL® Foley catheter straight	FOLYSIL® catheter straight CH FR 16, silicone, 2-way	15/01/1998
HA6118	FOLYSIL® Foley catheter straight	FOLYSIL® catheter straight CH FR 18, silicone, 2-way	15/01/1998
HA6120	FOLYSIL® Foley catheter straight	FOLYSIL® catheter straight CH FR 20, silicone, 2-way	15/01/1998
HA6122	FOLYSIL® Foley catheter straight	FOLYSIL® catheter straight CH FR 22, silicone, 2-way	15/01/1998
HA6124	FOLYSIL® Foley catheter straight	FOLYSIL® catheter straight CH FR 24, silicone, 2-way	15/01/1998
HI6612	FOLYSIL® Foley catheter / grooved / 2- way / silicone	FOLYSIL® catheter grooved CH FR 12, silicone, 2-way, box of one	30/10/2014
HI6614	FOLYSIL® Foley catheter / grooved / 2- way / silicone	FOLYSIL® catheter grooved CH FR 14, silicone, 2-way, box of one	30/10/2014
HI6616	FOLYSIL® Foley catheter / grooved / 2- way / silicone	FOLYSIL® catheter grooved CH FR 16, silicone, 2-way, box of one	30/10/2014
HI6618	FOLYSIL® Foley catheter / grooved / 2- way / silicone	FOLYSIL® catheter grooved CH FR 18, silicone, 2-way , box of one	30/10/2014
HI6620	FOLYSIL® Foley catheter / grooved / 2- way / silicone	FOLYSIL® catheter grooved CH FR 20, silicone, 2-way, box of one	30/10/2014
HI6622	FOLYSIL® Foley catheter / grooved / 2- way / silicone	FOLYSIL® catheter grooved CH FR 22, silicone, 2-way, box of one	30/10/2014
HI6624	FOLYSIL® Foley catheter / grooved / 2- way / silicone	FOLYSIL® catheter grooved CH FR 24, silicone, 2-way, box of one	30/10/2014

HS6112	FOLYSIL® Foley catheter straight	FOLYSIL® catheter straight CH FR 12, silicone, 2-way	30/09/2003
HS6114	FOLYSIL® Foley catheter straight	FOLYSIL® catheter straight CH FR 14, silicone, 2-way	30/09/2003
HS6116	FOLYSIL® Foley catheter straight	FOLYSIL® catheter straight CH FR 16, silicone, 2-way	30/09/2003
HS6118	FOLYSIL® Foley catheter straight	FOLYSIL® catheter straight CH FR 18, silicone, 2-way	30/09/2003
HS6120	FOLYSIL® Foley catheter straight	FOLYSIL® catheter straight CH FR 20, silicone, 2-way	30/09/2003
HS6122	FOLYSIL® Foley catheter straight	FOLYSIL® catheter straight CH FR 22, silicone, 2-way	30/09/2003
HS6124	FOLYSIL® Foley catheter straight	FOLYSIL® catheter straight CH FR 24, silicone, 2-way	30/09/2003

Date: 10/10/2015 By: 
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