



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® LT Catheter, FOLYSIL® X-Tra 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.	182

The undersigned, Head of Regulatory Affairs, declares that the following devices:
FOLYSIL® LT Catheter, FOLYSIL® X-Tra 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: 24/09/1999

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

Description on Primary Packaging for

Product family:

Urinary Indwelling Catheters

Product name:

FOLYSIL® LT Catheter, FOLYSIL® X-Tra Catheter

Item number	Product name	Product description	Date of the original CE-marking
AA7106	FOLYSIL® LT / FOLEY CATHETER / PEDIATRIC / WITH INTRODUCER / 2-WAY / SILICONE	FOLYSIL® LT pediatric with introducer silicone CH FR 06	22/12/2000
AA7108	FOLYSIL® LT / FOLEY CATHETER / PEDIATRIC / WITH INTRODUCER / 2-WAY / SILICONE	FOLYSIL® LT pediatric with introducer silicone CH FR 08	22/12/2000
AA7110	FOLYSIL® LT / FOLEY CATHETER / PEDIATRIC / WITH INTRODUCER / 2-WAY / SILICONE	FOLYSIL® LT pediatric with introducer silicone CH FR 10	22/12/2000
AA7112	FOLYSIL® LT / SILICONE / FOLEY CATHETER / 2-WAY	FOLYSIL® LT catheter straight tip silicone CH FR 12	22/12/2000
AA7114	FOLYSIL® LT / SILICONE / FOLEY CATHETER / 2-WAY	FOLYSIL® LT catheter straight tip silicone CH FR 14	22/12/2000
AA7116	FOLYSIL® LT / SILICONE / FOLEY CATHETER / 2-WAY	FOLYSIL® LT catheter straight tip silicone CH FR 16	22/12/2000
AA7118	FOLYSIL® LT / SILICONE / FOLEY CATHETER / 2-WAY	FOLYSIL® LT catheter straight tip silicone CH FR 18	22/12/2000
AA7120	FOLYSIL® LT / SILICONE / FOLEY CATHETER / 2-WAY	FOLYSIL® LT catheter straight tip silicone CH FR 20	22/12/2000
AA7122	FOLYSIL® LT / SILICONE / FOLEY CATHETER / 2-WAY	FOLYSIL® LT catheter straight tip silicone CH FR 22	22/12/2000
AA7412	FOLYSIL® LT / FOLEY CATHETER / OVER THE GUIDE / 2-WAY / SILICONE	FOLYSIL® LT over the guide catheter silicone CH FR 12	24/09/1999
AA7414	FOLYSIL® LT / FOLEY CATHETER / OVER THE GUIDE / 2-WAY / SILICONE	FOLYSIL® LT over the guide catheter silicone CH FR 14	24/09/1999
AA7416	FOLYSIL® LT / FOLEY CATHETER / OVER THE GUIDE / 2-WAY / SILICONE	FOLYSIL® LT over the guide catheter silicone CH FR 16	24/09/1999
AA7418	FOLYSIL® LT / FOLEY CATHETER / OVER THE GUIDE / 2-WAY / SILICONE	FOLYSIL® LT over the guide catheter silicone CH FR 18	24/09/1999
AA7420	FOLYSIL® LT / FOLEY CATHETER / OVER THE GUIDE / 2-WAY / SILICONE	FOLYSIL® LT over the guide catheter silicone CH FR 20	24/09/1999
AA7512	FOLYSIL® LT / FOLEY CATHETER / FEMALE / 2-WAY / SILICONE	FOLYSIL® LT catheter female silicone CH FR 12	24/09/1999
AA7514	FOLYSIL® LT / FOLEY CATHETER / FEMALE / 2-WAY / SILICONE	FOLYSIL® LT catheter female silicone CH FR 14	24/09/1999
AA7516	FOLYSIL® LT / FOLEY CATHETER / FEMALE / 2-WAY / SILICONE	FOLYSIL® LT catheter female silicone CH FR 16	24/09/1999

AA7518	FOLYSIL® LT / FOLEY CATHETER / FEMALE / 2-WAY / SILICONE	FOLYSIL® LT catheter female silicone CH FR 18	24/09/1999
AA8112	FOLYSIL® X-TRA CATHETER / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter straight tip silicone CH FR 12 with 10 ml syringe (water + 10% glycerine)	04/06/2004
AA8114	FOLYSIL® X-TRA CATHETER / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter straight tip silicone CH FR 14 with 10 ml syringe (water + 10% glycerine)	04/06/2004
AA8116	FOLYSIL® X-TRA CATHETER / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter straight tip silicone CH FR 16 with 10 ml syringe (water + 10% glycerine)	04/06/2004
AA8118	FOLYSIL® X-TRA CATHETER / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter straight tip silicone CH FR 18 with 10 ml syringe (water + 10% glycerine)	04/06/2004
AA8120	FOLYSIL® X-TRA CATHETER / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter straight tip silicone CH FR 20 with 10 ml syringe (water + 10% glycerine)	04/06/2004
AA8122	FOLYSIL® X-TRA CATHETER / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter straight tip silicone CH FR 22 with 10 ml syringe (water + 10% glycerine)	04/06/2004
AA8512	FOLYSIL® X-TRA CATHETER / FEMALE / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter female silicone CH FR 12 with 10 ml syringe (water + 10% glycerine)	04/06/2004
AA8514	FOLYSIL® X-TRA CATHETER / FEMALE / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter female silicone CH FR 14 with 10 ml syringe (water + 10% glycerine)	04/06/2004
AA8516	FOLYSIL® X-TRA CATHETER / FEMALE / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter female silicone CH FR 16 with 10 ml syringe (water + 10% glycerine)	04/06/2004
AA8518	FOLYSIL® X-TRA CATHETER / FEMALE / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter female silicone CH FR 18 with 10 ml syringe (water + 10% glycerine)	04/06/2004
AA8A12	FOLYSIL® X-TRA CATHETER / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter straight tip silicone CH FR 12 with 10 ml syringe (water + 10% glycerine) and 10 ml empty syringe	29/05/2009
AA8A14	FOLYSIL® X-TRA CATHETER / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter straight tip silicone CH FR 14 with 10 ml syringe (water + 10% glycerine) and 10 ml empty syringe	29/05/2009
AA8A16	FOLYSIL® X-TRA CATHETER / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter straight tip silicone CH FR 16 with 10 ml syringe (water + 10% glycerine) and 10 ml empty syringe	29/05/2009
AA8A18	FOLYSIL® X-TRA CATHETER / 2-WAY / SILICONE		29/05/2009

		FOLYSIL® X-Tra catheter straight tip silicone CH FR 18 with 10 ml syringe (water + 10% glycerine) and 10 ml empty syringe	
AA8A20	FOLYSIL® X-TRA CATHETER / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter straight tip silicone CH FR 20 with 10 ml syringe (water + 10% glycerine) and 10 ml empty syringe	29/05/2009
AA8A22	FOLYSIL® X-TRA CATHETER / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter straight tip silicone CH FR 22 with 10 ml syringe (water + 10% glycerine) and 10 ml empty syringe	29/05/2009
AA8B12	FOLYSIL® X-TRA CATHETER / FEMALE / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter female silicone CH FR 12 with 10 ml syringe (water + 10% glycerine) and 10 ml empty syringe	29/05/2009
AA8B14	FOLYSIL® X-TRA CATHETER / FEMALE / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter female silicone CH FR 14 with 10 ml syringe (water + 10% glycerine) and 10 ml empty syringe	29/05/2009
AA8B16	FOLYSIL® X-TRA CATHETER / FEMALE / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter female silicone CH FR 16 with 10 ml syringe (water + 10% glycerine) and 10 ml empty syringe	29/05/2009
AA8B18	FOLYSIL® X-TRA CATHETER / FEMALE / 2-WAY / SILICONE	FOLYSIL® X-Tra catheter female silicone CH FR 18 with 10 ml syringe (water + 10% glycerine) and 10 ml empty syringe	29/05/2009
AA8C12	FOLYSIL® X-TRA CATHETER / OPEN END / 2-WAY / SILICONE	FOLYSIL® X-Tra over the guide catheter silicone CH FR 12 with 10 ml syringe (water + 10% glycerine) and 10 ml empty syringe	29/05/2009
AA8C14	FOLYSIL® X-TRA CATHETER / OPEN END / 2-WAY / SILICONE	FOLYSIL® X-Tra over the guide catheter silicone CH FR 14 with 10 ml syringe (water + 10% glycerine) and 10 ml empty syringe	29/05/2009
AA8C16	FOLYSIL® X-TRA CATHETER / OPEN END / 2-WAY / SILICONE	FOLYSIL® X-Tra over the guide catheter silicone CH FR 16 with 10 ml syringe (water + 10% glycerine) and 10 ml empty syringe	29/05/2009
AA8C18	FOLYSIL® X-TRA CATHETER / OPEN END / 2-WAY / SILICONE		29/05/2009

FOLYSIL® X-Tra over the
guide catheter silicone CH
FR 18 with 10 ml syringe
(water + 10% glycerine) and
10 ml empty syringe

Date: 02/12/2016

By: 

Sihem Darraji

Head of Regulatory Affairs