



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: FOLATEX® Foley Catheter - Soft Latex
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 IIa Rule no.: 5
Notified Body	Presafe Denmark A/S - (0543) Tuborg Parkvej 8, DK-2900 Hellerup, Denmark
ID no.	177

The undersigned, Head of Regulatory Affairs, declares that the following devices:
FOLATEX® Foley Catheter - Soft Latex
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: 02/09/2004

Date: 13/03/2018

By: 

Sihem Darraji
Head of Regulatory Affairs



Description on Primary Packaging for

Product family:

Urinary Indwelling Catheters

Product name:

FOLATEX® Foley Catheter - Soft Latex

Item number	Product name	Product description	Date of the original CE-marking
AA1412	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 12	02/05/2011
AA1414	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 14	02/05/2011
AA1416	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 16	02/05/2011
AA1418	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 18	02/05/2011
AA1420	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 20	02/05/2011
AA1422	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 22	02/05/2011
AA1424	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 24	02/05/2011
AA1426	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 26	02/05/2011
AA1428	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 28	02/05/2011
AA1430	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 30	02/05/2011
AA1512	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, rubber valve, CH FR 12	02/05/2011
AA1514	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, rubber valve, CH FR 14	02/05/2011
AA1516	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, rubber valve, CH FR 16	02/05/2011
AA1518	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter 5-15 ml, rubber valve, CH FR 18	02/05/2011
			02/05/2011

AA1520	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, rubber valve, CH FR 20	
AA1522	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, rubber valve, CH FR 22	02/05/2011
AA1524	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter 5-15 ml, rubber valve, CH FR 24	02/05/2011
AA1526	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter 5-15 ml, rubber valve, CH FR 26	02/05/2011
AA1528	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, rubber valve, CH FR 28	02/05/2011
AA1530	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, rubber valve, CH FR 30	02/05/2011
AA1612	FOLATEX® Silicone coated latex urinary catheter/Tiemann/2-way	FOLATEX® Foley catheter Tiemann 5-15 ml, plastic valve, CH FR 12	02/09/2004
AA1614	FOLATEX® Silicone coated latex urinary catheter/Tiemann/2-way	FOLATEX® Foley catheter Tiemann 5-15 ml, plastic valve, CH FR 14	02/09/2004
AA1616	FOLATEX® Silicone coated latex urinary catheter/Tiemann/2-way	FOLATEX® Foley catheter Tiemann 5-15 ml, plastic valve, CH FR 16	02/09/2004
AA1618	FOLATEX® Silicone coated latex urinary catheter/Tiemann/2-way	FOLATEX® Foley catheter Tiemann 5-15 ml, plastic valve, CH FR 18	02/09/2004
AA1620	FOLATEX® Silicone coated latex urinary catheter/Tiemann/2-way	FOLATEX® Foley catheter Tiemann 5-15 ml, plastic valve, CH FR 20	02/09/2004
AA1622	FOLATEX® Silicone coated latex urinary catheter/Tiemann/2-way	FOLATEX® Foley catheter Tiemann 5-15 ml, plastic valve, CH FR 22	02/09/2004
AA1624	FOLATEX® Silicone coated latex urinary catheter/Tiemann/2-way	FOLATEX® Foley catheter Tiemann 5-15 ml, plastic valve, CH FR 24	02/09/2004
AA1B12	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 30 ml, plastic valve, CH FR 12	02/05/2011
AA1B14	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 30 ml, plastic valve, CH FR 14	02/05/2011
AA1B16	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 30-45 ml, plastic valve, CH FR 16	02/05/2011
AA1B18	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 30-45 ml, plastic valve, CH FR 18	02/05/2011
AA1B20	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 30-45 ml, plastic valve, CH FR 20	02/05/2011
AA1B22	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 30-45 ml, plastic valve, CH FR 22	02/05/2011
AA1B24	FOLATEX® Silicone coated latex urinary		02/05/2011

	catheter/Straight/2-way	FOLATEX® Foley catheter straight 30-45 ml, plastic valve, CH FR 24	
AA1B26	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 30-45 ml, plastic valve, CH FR 26	02/05/2011
AA1B28	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 30-45 ml, plastic valve, CH FR 28	02/05/2011
AA1B30	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 30-45 ml, plastic valve, CH FR 30	02/05/2011
AA3112	FOLATEX® Silicone coated latex urinary catheter /female/straight/2-way	FOLATEX® Foley catheter straight female 5-15 ml, plastic valve, CH FR 12	02/05/2011
AA3114	FOLATEX® Silicone coated latex urinary catheter /female/straight/2-way	FOLATEX® Foley catheter straight female 5-15 ml, plastic valve, CH FR 14	02/05/2011
AA3116	FOLATEX® Silicone coated latex urinary catheter /female/straight/2-way	FOLATEX® Foley catheter straight female 5-15 ml, plastic valve, CH FR 16	02/05/2011
AA3118	FOLATEX® Silicone coated latex urinary catheter /female/straight/2-way	FOLATEX® Foley catheter straight female 5-15 ml, plastic valve, CH FR 18	02/05/2011
AA3120	FOLATEX® Silicone coated latex urinary catheter /female/straight/2-way	FOLATEX® Foley catheter straight female 5-15 ml, plastic valve, CH FR 20	02/05/2011
AP1408	FOLATEX® Silicone coated latex urinary catheter /paediatric with Stylet/2-way	FOLATEX® Foley straight catheter Paediatric 3 ml, plastic valve, CH FR 08	27/10/2004
AP1410	FOLATEX® Silicone coated latex urinary catheter /paediatric with Stylet/2-way	FOLATEX® Foley straight catheter Paediatric 3 ml, plastic valve, CH FR 10	27/10/2004
HA1412	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 12	10/02/2005
HA1414	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 14	10/02/2005
HA1416	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 16	10/02/2005
HA1418	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 18	10/02/2005
HA1420	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 20	10/02/2005
HA1422	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 22	10/02/2005
HA1424	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 24	10/02/2005
HA1426	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 26	10/02/2005
HA1428	FOLATEX® Silicone coated latex urinary		10/02/2005

	catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 28	
HA1430	FOLATEX® Silicone coated latex urinary catheter/Straight/2-way	FOLATEX® Foley catheter straight 5-15 ml, plastic valve, CH FR 30	10/02/2005
HA3112	FOLATEX® Silicone coated latex urinary catheter /female/straight/2-way	FOLATEX® Foley catheter straight female 5-15 ml, plastic valve, CH FR 12	10/02/2005
HA3114	FOLATEX® Silicone coated latex urinary catheter /female/straight/2-way	FOLATEX® Foley catheter straight female 5-15 ml, plastic valve, CH FR 14	10/02/2005
HA3116	FOLATEX® Silicone coated latex urinary catheter /female/straight/2-way	FOLATEX® Foley catheter straight female 5-15 ml, plastic valve, CH FR 16	10/02/2005
HA3118	FOLATEX® Silicone coated latex urinary catheter /female/straight/2-way	FOLATEX® Foley catheter straight female 5-15 ml, plastic valve, CH FR 18	10/02/2005
HA3120	FOLATEX® Silicone coated latex urinary catheter /female/straight/2-way	FOLATEX® Foley catheter straight female 5-15 ml, plastic valve, CH FR 20	10/02/2005
HA3122	FOLATEX® Silicone coated latex urinary catheter /female/straight/2-way	FOLATEX® Foley catheter straight female 5-15 ml, plastic valve, CH FR 22	10/02/2005
HA3714	FOLATEX® Silicone coated latex urinary catheter/Tiemann/2-way	FOLATEX® Foley catheter Tiemann 5-15 ml, plastic valve, CH FR 14	10/02/2005
HA3716	FOLATEX® Silicone coated latex urinary catheter/Tiemann/2-way	FOLATEX® Foley catheter Tiemann 5-15 ml, plastic valve, CH FR 16	10/02/2005
HA3718	FOLATEX® Silicone coated latex urinary catheter/Tiemann/2-way	FOLATEX® Foley catheter Tiemann 5-15 ml, plastic valve, CH FR 18	10/02/2005
HA3720	FOLATEX® Silicone coated latex urinary catheter/Tiemann/2-way	FOLATEX® Foley catheter Tiemann 5-15 ml, plastic valve, CH FR 20	10/02/2005
QSM130	FOLATEX® Silicone coated latex urinary catheter /straight/2-way	FOLATEX® Foley catheter straight 75 ml, plastic valve, CH FR 30	11/05/2005

Date: 13/03/2018 By: 
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