



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: Guyon Catheter, Catheter Whistle Tip, Nelaton Catheter, Straight Olive Tip Catheter, Mercier Catheter, Bazy Catheter, Tiemann Catheter, Marion Catheter, Gouverneur Catheter
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 IIa Rule no.: 5
Notified Body	Danish Medical Devices Certification (DGM) 0543
ID no.	189

The undersigned, Director, Regulatory Affairs, declares that:

Guyon Catheter, Catheter Whistle Tip, Nelaton Catheter, Straight Olive Tip Catheter, Mercier Catheter, Bazy Catheter, Tiemann Catheter, Marion Catheter, Gouverneur Catheter conforms to the relevant provisions of the European Communities' Council Directive 93/42/EEC and amendments and is in accordance with:

Annex II Conformity Assessment Procedure (full quality assurance system) as verified by the Danish Medical Devices Certification (DGM) 0543.

This product was originally CE-marked: 04/02/1998

Date: **23 OCT 2014**

By: _____

Joan Drejer

Director, Regulatory Affairs

Description on Primary Packaging for

Product family:

Urinary Indwelling Catheters

Product name:

Guyon Catheter, Catheter Whistle Tip, Nelaton Catheter, Straight Olive Tip Catheter, Mercier Catheter, Bazy Catheter, Tiemann Catheter, Marion Catheter, Gouverneur Catheter

Item number	Product name	Product description	Date of the original CE-marking
AD5B12	GUYON CATHETER	Guyon catheter, straight open ended, Neoplex, length 34 cm, CH FR 12	04-02-1998
AD5B14	GUYON CATHETER	Guyon catheter, straight open ended, Neoplex, length 34 cm, CH FR 14	04-02-1998
AD5B16	GUYON CATHETER	Guyon catheter, straight open ended, Neoplex, length 34 cm, CH FR 16	04-02-1998
AD5B18	GUYON CATHETER	Guyon catheter, straight open ended, Neoplex, length 34 cm, CH FR 18	04-02-1998
AD5D06	CATHETER WHISTLE TIP / 2 EYES	Couvelaire straight whistle tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 06	04-02-1998
AD5D08	CATHETER WHISTLE TIP / 2 EYES	Couvelaire straight whistle tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 08	04-02-1998
AD5D10	CATHETER WHISTLE TIP / 2 EYES	Couvelaire straight whistle tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 10	04-02-1998
AD5D12	CATHETER WHISTLE TIP / 2 EYES	Couvelaire straight whistle tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 12	04-02-1998
AD5D14	CATHETER WHISTLE TIP / 2 EYES	Couvelaire straight whistle tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 14	04-02-1998
AD5D16	CATHETER WHISTLE TIP / 2 EYES	Couvelaire straight whistle tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 16	04-02-1998
AD5D18	CATHETER WHISTLE TIP / 2 EYES	Couvelaire straight whistle tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 18	04-02-1998
AD5D20	CATHETER WHISTLE TIP / 2 EYES		04-02-1998

		Couvelaire straight whistle tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 20	
AD5D22	CATHETER WHISTLE TIP / 2 EYES	Couvelaire straight whistle tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 22	04-02-1998
AD5D24	CATHETER WHISTLE TIP / 2 EYES	Couvelaire straight whistle tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 24	04-02-1998
AD5D26	CATHETER WHISTLE TIP / 2 EYES	Couvelaire straight whistle tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 26	04-02-1998
ADN006	NELATON CATHETER / 2 EYES	Nelaton straight tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 06	04-02-1998
ADN008	NELATON CATHETER / 2 EYES	Nelaton straight tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 08	04-02-1998
ADN010	NELATON CATHETER / 2 EYES	Nelaton straight tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 10	04-02-1998
ADN012	NELATON CATHETER / 2 EYES	Nelaton straight tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 12	04-02-1998
ADN014	NELATON CATHETER / 2 EYES	Nelaton straight tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 14	04-02-1998
ADN016	NELATON CATHETER / 2 EYES	Nelaton straight tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 16	04-02-1998
ADN018	NELATON CATHETER / 2 EYES	Nelaton straight tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 18	04-02-1998
ADN020	NELATON CATHETER / 2 EYES	Nelaton straight tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 20	04-02-1998
ADN022	NELATON CATHETER / 2 EYES	Nelaton straight tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 22	04-02-1998
ADN024	NELATON CATHETER / 2 EYES	Nelaton straight tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 24	04-02-1998
ADN106	STRAIGHT OLIVE TIP CATHETER / 2 EYES	Straight olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 06	04-02-1998

ADN108	STRAIGHT OLIVE TIP CATHETER / 2 EYES	Straight olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 08	04-02-1998
ADN110	STRAIGHT OLIVE TIP CATHETER / 2 EYES	Straight olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 10	04-02-1998
ADN112	STRAIGHT OLIVE TIP CATHETER / 2 EYES	Straight olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 12	04-02-1998
ADN114	STRAIGHT OLIVE TIP CATHETER / 2 EYES	Straight olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 14	04-02-1998
ADN116	STRAIGHT OLIVE TIP CATHETER / 2 EYES	Straight olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 16	04-02-1998
ADN118	STRAIGHT OLIVE TIP CATHETER / 2 EYES	Straight olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 18	04-02-1998
ADN120	STRAIGHT OLIVE TIP CATHETER / 2 EYES	Straight olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 20	04-02-1998
ADN122	STRAIGHT OLIVE TIP CATHETER / 2 EYES	Straight olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 22	04-02-1998
ADN124	STRAIGHT OLIVE TIP CATHETER / 2 EYES	Straight olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 24	04-02-1998
ADN306	MERCIER CATHETER / 2 EYES	Mercier coude tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 06	04-02-1998
ADN308	MERCIER CATHETER / 2 EYES	Mercier coude tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 08	04-02-1998
ADN310	MERCIER CATHETER / 2 EYES	Mercier coude tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 10	04-02-1998
ADN312	MERCIER CATHETER / 2 EYES	Mercier coude tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 12	04-02-1998
ADN314	MERCIER CATHETER / 2 EYES	Mercier coude tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 14	04-02-1998
ADN316	MERCIER CATHETER / 2 EYES	Mercier coude tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 16	04-02-1998
ADN318	MERCIER CATHETER / 2 EYES	Mercier coude tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 18	04-02-1998
ADN320	MERCIER CATHETER / 2 EYES	Mercier coude tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 20	04-02-1998

ADN322	MERCIER CATHETER / 2 EYES	Mercier coude tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 22	04-02-1998
ADN324	MERCIER CATHETER / 2 EYES	Mercier coude tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 24	04-02-1998
ADN326	MERCIER CATHETER / 2 EYES	Mercier coude tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 26	04-02-1998
ADN410	BAZY CATHETER / 5 EYES	Bazy coude tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 10	04-02-1998
ADN412	BAZY CATHETER / 5 EYES	Bazy coude tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 12	04-02-1998
ADN414	BAZY CATHETER / 5 EYES	Bazy coude tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 14	04-02-1998
ADN416	BAZY CATHETER / 5 EYES	Bazy coude tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 16	04-02-1998
ADN418	BAZY CATHETER / 5 EYES	Bazy coude tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 18	04-02-1998
ADN420	BAZY CATHETER / 5 EYES	Bazy coude tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 20	04-02-1998
ADN422	BAZY CATHETER / 5 EYES	Bazy coude tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 22	04-02-1998
ADN424	BAZY CATHETER / 5 EYES	Bazy coude tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 24	04-02-1998
ADN506	TIEMANN CATHETER / 2 EYES	Tiemann coude olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 06	04-02-1998
ADN508	TIEMANN CATHETER / 2 EYES	Tiemann coude olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 08	04-02-1998
ADN510	TIEMANN CATHETER / 2 EYES	Tiemann coude olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 10	04-02-1998
ADN512	TIEMANN CATHETER / 2 EYES	Tiemann coude olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 12	04-02-1998
ADN514	TIEMANN CATHETER / 2 EYES	Tiemann coude olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 14	04-02-1998
ADN516	TIEMANN CATHETER / 2 EYES		04-02-1998

		Tiemann coude olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 16	
ADN518	TIEMANN CATHETER / 2 EYES	Tiemann coude olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 18	04-02-1998
ADN520	TIEMANN CATHETER / 2 EYES	Tiemann coude olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 20	04-02-1998
ADN522	TIEMANN CATHETER / 2 EYES	Tiemann coude olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 22	04-02-1998
ADN524	TIEMANN CATHETER / 2 EYES	Tiemann coude olive tip catheter, 2 eyes, Neoplex, length 40 cm, CH FR 24	04-02-1998
ADN610	MARION CATHETER / 5 EYES	Marion coude olive tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 10	04-02-1998
ADN612	MARION CATHETER / 5 EYES	Marion coude olive tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 12	04-02-1998
ADN614	MARION CATHETER / 5 EYES	Marion coude olive tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 14	04-02-1998
ADN616	MARION CATHETER / 5 EYES	Marion coude olive tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 16	04-02-1998
ADN618	MARION CATHETER / 5 EYES	Marion coude olive tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 18	04-02-1998
ADN620	MARION CATHETER / 5 EYES	Marion coude olive tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 20	04-02-1998
ADN622	MARION CATHETER / 5 EYES	Marion coude olive tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 22	04-02-1998
ADN624	MARION CATHETER / 5 EYES	Marion coude olive tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 24	04-02-1998
ADN912	GOUVERNEUR CATHETER / 5 EYES	Gouverneur straight whistle tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 12	04-02-1998
ADN914	GOUVERNEUR CATHETER / 5 EYES		04-02-1998

		Gouverneur straight whistle tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 14	
ADN916	GOUVERNEUR CATHETER / 5 EYES	Gouverneur straight whistle tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 16	04-02-1998
ADN918	GOUVERNEUR CATHETER / 5 EYES	Gouverneur straight whistle tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 18	04-02-1998
ADN920	GOUVERNEUR CATHETER / 5 EYES	Gouverneur straight whistle tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 20	04-02-1998
ADN922	GOUVERNEUR CATHETER / 5 EYES	Gouverneur straight whistle tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 22	04-02-1998
ADN924	GOUVERNEUR CATHETER / 5 EYES	Gouverneur straight whistle tip catheter, 5 eyes, Neoplex, length 40 cm, CH FR 24	04-02-1998

Date **23 OCT 2014**

By: _____

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