

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: Urological Accessories (sterile)
	Product name: Urethral Bougie, single use
Description	On primary packaging: See attachment
	Global Medical Device Nomenclature code/name: 47238 Urethral bougie, single-use
EC Product Class according to Annex IX	Class: Sterile class I Rule no.: 5
Notified Body	Danish Medical Devices Certification (DGM) 0543
ID no.	275

The undersigned, Director, Regulatory Affairs, declares that:

Urethral Bougie, single use

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: 03/12/1998

Date: **10 DEC 2014**

By: _____

Joan Drejer

Director, Regulatory Affairs

Description on Primary Packaging for

Product family:

Urological Accessories (sterile)

Product name:

Urethral Bougie, single use

Item number	Product name	Product description	Date of the original CE-marking
AG5003	EXPLORATORY FILIFORM BOUGIE STRAIGHT OLIVARY	Exploratory filiform bougie straight olivary CH FR 03	24-02-1998
AG5004	EXPLORATORY FILIFORM BOUGIE STRAIGHT OLIVARY	Exploratory filiform bougie straight olivary CH FR 04	24-02-1998
AG5005	EXPLORATORY FILIFORM BOUGIE STRAIGHT OLIVARY	Exploratory filiform bougie straight olivary CH FR 05	24-02-1998
AG5006	EXPLORATORY FILIFORM BOUGIE STRAIGHT OLIVARY	Exploratory filiform bougie straight olivary CH FR 06	24-02-1998
AG5007	EXPLORATORY FILIFORM BOUGIE STRAIGHT OLIVARY	Exploratory filiform bougie straight olivary CH FR 07	24-02-1998
AG5103	FILIFORM BOUGIE STRAIGHT MALE METRIC THREAD	Filiform bougie straight male metric thread CH FR 03	24-02-1998
AG5104	FILIFORM BOUGIE STRAIGHT MALE METRIC THREAD	Filiform bougie straight male metric thread CH FR 04	24-02-1998
AG5105	FILIFORM BOUGIE STRAIGHT MALE METRIC THREAD	Filiform bougie straight male metric thread CH FR 05	24-02-1998
AG5106	FILIFORM BOUGIE STRAIGHT MALE METRIC THREAD	Filiform bougie straight male metric thread CH FR 06	24-02-1998
AG5107	FILIFORM BOUGIE STRAIGHT MALE METRIC THREAD	Filiform bougie straight male metric thread CH FR 07	24-02-1998
AG5206	GUYON EXPLORATORY BOUGIE	Guyon exploratory bougie CH FR 06	24-02-1998
AG5208	GUYON EXPLORATORY BOUGIE	Guyon exploratory bougie CH FR 08	24-02-1998
AG5210	GUYON EXPLORATORY BOUGIE	Guyon exploratory bougie CH FR 10	24-02-1998
AG5212	GUYON EXPLORATORY BOUGIE	Guyon exploratory bougie CH FR 12	24-02-1998
AG5214	GUYON EXPLORATORY BOUGIE	Guyon exploratory bougie CH FR 14	24-02-1998
AG5216	GUYON EXPLORATORY BOUGIE	Guyon exploratory bougie CH FR 16	24-02-1998
AG5218	GUYON EXPLORATORY BOUGIE	Guyon exploratory bougie CH FR 18	24-02-1998
AG5220	GUYON EXPLORATORY BOUGIE	Guyon exploratory bougie CH FR 20	24-02-1998
AG5222	GUYON EXPLORATORY BOUGIE	Guyon exploratory bougie CH FR 22	24-02-1998
AG5224	GUYON EXPLORATORY BOUGIE	Guyon exploratory bougie CH FR 24	24-02-1998

AG5226	GUYON EXPLORATORY BOUGIE	Guyon exploratory bougie CH FR 26	24-02-1998
AG5228	GUYON EXPLORATORY BOUGIE	Guyon exploratory bougie CH FR 28	24-02-1998
AG5230	GUYON EXPLORATORY BOUGIE	Guyon exploratory bougie CH FR 30	24-02-1998
AG5306	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 06	24-02-1998
AG5307	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 07	24-02-1998
AG5308	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 08	24-02-1998
AG5309	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 09	24-02-1998
AG5310	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 10	24-02-1998
AG5312	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 12	24-02-1998
AG5314	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 14	24-02-1998
AG5316	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 16	24-02-1998
AG5318	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 18	24-02-1998
AG5320	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 20	24-02-1998
AG5322	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 22	24-02-1998
AG5324	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 24	24-02-1998
AG5326	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 26	24-02-1998
AG5328	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 28	24-02-1998
AG5330	STRAIGHT TAPERED OLIVE TIP BOUGIE	Straight tapered olive tip bougie CH FR 30	24-02-1998
AG5408	PHILIPS BOUGIE FEMALE METRIC THREAD	Philips bougie female metric thread CH FR 08	24-02-1998
AG5410	PHILIPS BOUGIE FEMALE METRIC THREAD	Philips bougie female metric thread CH FR 10	24-02-1998
AG5412	PHILIPS BOUGIE FEMALE METRIC THREAD	Philips bougie female metric thread CH FR 12	24-02-1998
AG5414	PHILIPS BOUGIE FEMALE METRIC THREAD	Philips bougie female metric thread CH FR 14	24-02-1998
AG5416	PHILIPS BOUGIE FEMALE METRIC THREAD	Philips bougie female metric thread CH FR 16	24-02-1998
AG5418	PHILIPS BOUGIE FEMALE METRIC THREAD	Philips bougie female metric thread CH FR 18	24-02-1998
AG5420	PHILIPS BOUGIE FEMALE METRIC THREAD	Philips bougie female metric thread CH FR 20	24-02-1998
AG5422	PHILIPS BOUGIE FEMALE METRIC THREAD	Philips bougie female metric thread CH FR 22	24-02-1998
AG5424	PHILIPS BOUGIE FEMALE METRIC THREAD	Philips bougie female metric thread CH FR 24	24-02-1998
AG5903	FILIFORM BOUGIE STRAIGHT MALE		24-02-1998

	METRIC THREAD	Filiform bougie straight male metric thread CH FR 03	
AG5904	FILIFORM BOUGIE STRAIGHT MALE METRIC THREAD	Filiform bougie straight male metric thread CH FR 04	24-02-1998
AG5905	FILIFORM BOUGIE STRAIGHT MALE METRIC THREAD	Filiform bougie straight male metric thread CH FR 05	24-02-1998
AG5906	FILIFORM BOUGIE STRAIGHT MALE METRIC THREAD	Filiform bougie straight male metric thread CH FR 06	24-02-1998
AG5F03	FILIFORM BOUGIE SPIRAL MALE METRIC THREAD	Filiform bougie spiral male metric thread CH FR 03	22-01-1998
AG5F04	FILIFORM BOUGIE SPIRAL MALE METRIC THREAD	Filiform bougie spiral male metric thread CH FR 04	22-01-1998
AG5F05	FILIFORM BOUGIE SPIRAL MALE METRIC THREAD	Filiform bougie spiral male metric thread CH FR 05	22-01-1998
AG5F06	FILIFORM BOUGIE SPIRAL MALE METRIC THREAD	Filiform bougie spiral male metric thread CH FR 06	22-01-1998
AG5J03	FILIFORM BOUGIE COUDE TIP MALE METRIC THREAD	Filiform bougie coude tip male metric thread CH FR 03	24-02-1998
AG5J04	FILIFORM BOUGIE COUDE TIP MALE METRIC THREAD	Filiform bougie coude tip male metric thread CH FR 04	24-02-1998
AG5J05	FILIFORM BOUGIE COUDE TIP MALE METRIC THREAD	Filiform bougie coude tip male metric thread CH FR 05	24-02-1998
AG5J06	FILIFORM BOUGIE COUDE TIP MALE METRIC THREAD	Filiform bougie coude tip male metric thread CH FR 06	24-02-1998
AG5J07	FILIFORM BOUGIE COUDE TIP MALE METRIC THREAD	Filiform bougie coude tip male metric thread CH FR 07	24-02-1998
AG7308	URETHRAL BOUGIE / PVC	Urethral bougie straight tapered olive tip CH FR 08	03-12-1998
AG7310	URETHRAL BOUGIE / PVC	Urethral bougie straight tapered olive tip CH FR 10	03-12-1998
AG7312	URETHRAL BOUGIE / PVC	Urethral bougie straight tapered olive tip CH FR 12	03-12-1998
AG7314	URETHRAL BOUGIE / PVC	Urethral bougie straight tapered olive tip CH FR 14	03-12-1998
AG7316	URETHRAL BOUGIE / PVC	Urethral bougie straight tapered olive tip CH FR 16	03-12-1998
AG7318	URETHRAL BOUGIE / PVC	Urethral bougie straight tapered olive tip CH FR 18	03-12-1998
AG7320	URETHRAL BOUGIE / PVC	Urethral bougie straight tapered olive tip CH FR 20	03-12-1998
AG7322	URETHRAL BOUGIE / PVC	Urethral bougie straight tapered olive tip CH FR 22	03-12-1998
AG7324	URETHRAL BOUGIE / PVC	Urethral bougie straight tapered olive tip CH FR 24	03-12-1998
AG7326	URETHRAL BOUGIE / PVC	Urethral bougie straight tapered olive tip CH FR 26	03-12-1998
AG7328	URETHRAL BOUGIE / PVC	Urethral bougie straight tapered olive tip CH FR 28	03-12-1998
AG7330	URETHRAL BOUGIE / PVC	Urethral bougie straight tapered olive tip CH FR 30	03-12-1998
YG7312	DILATING BOUGIE / PVC	Dilating bougie straight tapered olive tip CH FR 12	03-12-1998
YG7314	DILATING BOUGIE / PVC	Dilating bougie straight tapered olive tip CH FR 14	03-12-1998
YG7316	DILATING BOUGIE / PVC		03-12-1998

		Dilating bougie straight tapered olive tip CH FR 16	
YG7318	DILATING BOUGIE / PVC	Dilating bougie straight tapered olive tip CH FR 18	03-12-1998
YG7320	DILATING BOUGIE / PVC	Dilating bougie straight tapered olive tip CH FR 20	03-12-1998
YG7322	DILATING BOUGIE / PVC	Dilating bougie straight tapered olive tip CH FR 22	03-12-1998
YG7324	DILATING BOUGIE / PVC	Dilating bougie straight tapered olive tip CH FR 24	03-12-1998
YG7326	DILATING BOUGIE / PVC	Dilating bougie straight tapered olive tip CH FR 26	03-12-1998
YG7328	DILATING BOUGIE / PVC	Dilating bougie straight tapered olive tip CH FR 28	03-12-1998
YG7330	DILATING BOUGIE / PVC	Dilating bougie straight tapered olive tip CH FR 30	03-12-1998

Date: **10 DEC 2014** By: 
Joan Drejer
Director, Regulatory Affairs