



## EC DECLARATION OF CONFORMITY With regard to MDD 93/42/EEC as amended for medical devices

Name of the Company : MEDPRO MEDICAL B.V

List of Products : Ureteral Balloon Dilation Catheter, Ureteral Dilator, Fascial Dilator, Nottingham Dilator, Meatal Dilator, Amplatz Renal Dilator Set, Urethral Filliform Dilator, Fascial Dilator Set, Ureteral Dilator Set, Urethral Dilator, Urethral Dilator Set, Renal Dilator.

Model/Type ref. : Refer page 2

Address : Landjuweel 11, 3905PE Veenendaal, Netherlands

*We hereby under our sole responsibility declare, that the product to which this declaration relates, is in conformity with the relevant provisions of standards and other normative document(s) and full fills the essential requirements of 93/42/EEC*

*We have presented our product and our system to notified body 3EC (2265) for conformity assessment as per Annexure II of MDD 93/42/EEC as amended by 2007/47/EC*

*This declaration is based on*

a) *EN ISO 15223-1:2012 EN 1041:2008, EN 556-1:2001, EN ISO 13485:2012, EN ISO 14971-2012, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-7:2008 EN ISO 10993-11:2009, ISO11607-1-2009, ISO14644-1, ISO 11135-1:2007 Harmonized Standards*

b) *Technical File. (QAD-TCF-UR-02)*



CERTIFICATE NUMBER	DATE OF ISSUE	VALIDITY
2014-MDD/QS-013	04-04-2014	27-02-2019

Place of Issue : Veenendaal  
Manufacturer : MEDPRO MEDICAL B.V

Signature :

Name : P. de Bruin

Position : Management Representative

Date : 08-04-2014

### PRODUCTS AND MODELS COVERED IN THE DECLARATION



S.No	List of Products	Classification rule	class
1	Ureteral Balloon Dilation Catheter	As per Rule 5 of Annex IX of MDD	Class IIa
2	Ureteral Dilator	As per Rule 5 of Annex IX of MDD	Class IIa
3	Fascial Dilator	As per Rule 7 of Annex IX of MDD	Class IIa
4	Nottingham Dilator	As per Rule 5 of Annex IX of MDD	Class IIa
5	Meatal Dilator	As per Rule 5 of Annex IX of MDD	Class IIa
6	Amplatz Renal Dilator Set	As per Rule 7 of Annex IX of MDD	Class IIa
7	Urethral Filliform Dilator	As per Rule 5 of Annex IX of MDD	Class IIa
8	Fascial Dilator Set	As per Rule 7 of Annex IX of MDD	Class IIa
9	Ureteral Dilator Set	As per Rule 5 of Annex IX of MDD	Class IIa
10	Urethral Dilator	As per Rule 5 of Annex IX of MDD	Class IIa
11	Urethral Dilator Set	As per Rule 5 of Annex IX of MDD	Class IIa
12	Renal Dilator	As per Rule 5 of Annex IX of MDD	Class IIa

## 1. URETERAL BALLOON DILATION CATHETER

FAMILY	SIZE ( Fr.)	LENGTH (CM)	TYPE
UBDC	5 6	70	-----

## 2. URETERAL DILATOR

FAMILY	SIZE ( Fr.)	LENGTH (CM)	TYPE
UD	6 8 10 12 14 16 18 20 22 24	70	-----



**3. FASCIAL DILATOR**

<b>FAMILY</b>	<b>SIZE ( Fr.)</b>	<b>LENGTH (CM)</b>	<b>TYPE</b>
FD	6 8 10 12 14 16 18 20 22 24	22	-----

**4. NOTTINGHAM DILATOR**

<b>FAMILY</b>	<b>SIZE ( Fr.)</b>	<b>LENGTH (CM)</b>	<b>TYPE</b>
ND	5/10 6/10 6/12 7/12 7/14 7/16 8/18	70	-----

**5. MEATAL DILATOR**

<b>FAMILY</b>	<b>SIZE (Fr.)</b>	<b>LENGTH (CM)</b>	<b>TYPE</b>
MD	6/16	-----	-----

**6. AMPLATZ RENAL DILATOR SET**

<b>FAMILY</b>	<b>SIZE (Fr.)</b>	<b>LENGTH (CM)</b>	<b>TYPE</b>
ARDSET	-----	-----	-----

**7. URETHRAL FILLIFORM DILATOR**

<b>FAMILY</b>	<b>SIZE (Fr.)</b>	<b>LENGTH (CM)</b>	<b>TYPE</b>
UTHFD	8/6 10/6 12/7 14/7 16/8 18/8 20/8 22/8	40	-----



**8. FASCIAL DILATOR SET**

<b>FAMILY</b>	<b>SIZE (Fr.)</b>	<b>LENGTH (CM)</b>	<b>TYPE</b>
FDS	6-16 6-10 8-14 18-24	22	-----

**9. URETERAL DILATOR SET**

<b>FAMILY</b>	<b>SIZE (Fr.)</b>	<b>LENGTH (CM)</b>	<b>TYPE</b>
UDS	6-16 6-24	70	-----

**10. URETHRAL DILATOR**

<b>FAMILY</b>	<b>SIZE (Fr.)</b>	<b>SIZE (Fr.)</b>	<b>SIZE (Fr.)</b>
UTHD	8 10 12 14 16 18 20 22	40	-----

**11. URETHRAL DILATOR SET**

	<b>SIZE (Fr.)</b>	<b>LENGTH (CM)</b>	<b>TYPE</b>
UTHDS	8-22	40	-----

**12. RENAL DILATOR**

	<b>SIZE (Fr.)</b>	<b>LENGTH (CM)</b>	<b>TYPE</b>
RD	18 20 22 24 26 28 30	30	-----