



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

Name of the Company : MEDPRO MEDICAL B.V

Product : Stone Basket-SS, Stone Basket- Nitinol, Stone Grasper, Bladder Evacuator, Track Finder Bulb Irrigator, Toomey Tip Syringe, TUR Set, Stent Remover

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-04)*



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

Place of Issue : Veenendaal

Manufacturer : MEDPRO MEDICAL B.V

Signature :

Name : P. de Bruin

Position : Management Representative

Date : 08-04-2014



## LIST OF PRODUCTS AND MODELS COVERED IN THE DECLARATION

S.No	List of Products	Classification rule	class
1	Stone Basket SS	As per Rule 5 of Annex IX of MDD	Class IIa
2	Stone Basket Nitinol	As per Rule 5 of Annex IX of MDD	Class IIa
3	Stone Grasper	As per Rule 5 of Annex IX of MDD	Class IIa
4	TUR Set	As per Rule 5 of Annex IX of MDD	Class IIa
5	Bladder Evacuator	As per Rule 2 of Annex IX of MDD	Class IIa
6	Track Finder Bulb Irrigator	As per Rule 2 of Annex IX of MDD	Class IIa
7	Toomey Tip Syringe	As per Rule 2 of Annex IX of MDD	Class IIa
8	Stent Remover	As per Rule 5 of Annex IX of MDD	Class IIa

### 1. STONE BASKET - SS

FAMILY	SIZE (FR.)	WIRE	LENGTH (CM)	TYPE	Tip
SBS	2.5	3	70	S H	T
	3	4	90		Z
	4	5	110		
	5				

### 2. STONE BASKET - NITINOL

FAMILY	SIZE (FR.)	WIRE	LENGTH (CM)	TYPE	Tip
SBN	2.5	3	70	S H	T
	3	4	90		Z
	4	5	110		
	5				

### 3. STONE GRASPER

FAMILY	SIZE (FR.)	LENGTH (CM)	TYPE	
SG	2.5	70	F T	F
	3	90		R
	4	110		
	5			



**4. TURSET**

<b>FAMILY</b>	<b>SIZE (FR)</b>	<b>LENGTH (CM)</b>	<b>TYPE</b>
TURSET	-----	-----	-----

**5. BLADDER EVACUATOR**

<b>FAMILY</b>	<b>SIZE (FR.)</b>	<b>LENGTH (CM)</b>	<b>TYPE</b>
BE	-----	-----	-----

**6. TRACK FINDER BULB IRRIGATOR**

<b>FAMILY</b>	<b>SIZE (FR.)</b>	<b>LENGTH (CM)</b>	<b>TYPE</b>
TFBI	-----	-----	-----

**7. TOOMEY TIP SYRINGE**

<b>FAMILY</b>	<b>VOLUME (CC)</b>	<b>LENGTH (CM)</b>	<b>TYPE</b>
TTS	70	-----	-----

**8. STENT REMOVER**

<b>FAMILY</b>	<b>SIZE (FR.)</b>	<b>LENGTH (CM)</b>	<b>TYPE</b>
SR	4 5	70	-----