



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 : Double J Stent, Mono J Stent, Guide Wire, Prostate Stent, Urethral Stent, Long Pusher for DJS, Loop Stent, Endopyelotomy Stent, Tumor Stent, Double J Stent Long Duro

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-05)*



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



LIST OF PRODUCTS COVERED IN THE DECLARATION

S.No	List of Products	Classification rule	class
1	Double J Stent	As per Rule 5 of Annex IX of MDD	Class IIa
2	Mono J stent	As per Rule 5 of Annex IX of MDD	Class IIa
3	Guide Wire	As per Rule 5 of Annex IX of MDD	Class IIa
4	Prostate Stent	As per Rule 5 of Annex IX of MDD	Class IIa
5	Urethral Stent	As per Rule 5 of Annex IX of MDD	Class IIa
6	Loop Stent	As per Rule 5 of Annex IX of MDD	Class IIa
7	Long Pusher for DJS	As per Rule 5 of Annex IX of MDD	Class IIa
8	Endopyelotomy Stent	As per Rule 5 of Annex IX of MDD	Class IIa
9	Tumor Stent	As per Rule 5 of Annex IX of MDD	Class IIa
10	Double J Stent Long Duro	As per Rule 5 of Annex IX of MDD	Class IIb

1. DOUBLE J STENT

FAMILY	SIZE (x0.1 FR)	LENGTH (CM)	TYPE	COLOR	OPTIONS
DJSBES DJSOEM DJSBEM	30	12 14 16 18 20 22 24 26 28 30	OEO BEO BEC	*B *G *W	/C /G /CG /S /SG /SC /SCG
	35				
	38				
	40				
	45				
	47				
	48				
	50				
	55				
	60				
	65				
70					
80					

2. MONO J STENT

FAMILY	SIZE (FR)	LENGTH (CM)	TYPE	COLOR
MJS	5 6 7	70	OEO BEO	*B *G *W



3. GUIDE WIRE

FAMILY	SIZE (Inch)	LENGTH (CM)	TYPE	MATERIAL
GW	0.018 0.025 0.028 0.032 0.035 0.038	(80 PTFE only) 150 (250 PTFE only)	J S	*BW *N *Z *PEG

4. PROSTATE STENT

FAMILY	SIZE (FR)	LENGTH (CM)	TYPE
PS	12 14 16	3 4 5	-----

5. URETHRAL STENT

FAMILY	SIZE (FR)	LENGTH (CM)	TYPE	COLOR
UTHS	5 6 7 8 10	25 30	-----	*B *G *W

6. LOOP STENT

FAMILY	SIZE (FR)	LENGTH (CM)	TYPE
LS	4 5 6	24 26 28 30	OEO BEO

7. LONG PUSHER FOR DJS

FAMILY	SIZE (X0.1 FR)	LENGTH (CM)	TYPE
PUSH	35 40 45 50 55 60 65 70 75 80	(X) All sizes	-----



8. ENDOPYELOTOMY STENT

FAMILY	SIZE (FR)	LENGTH (CM)	TYPE
ES	5/10	24	BEO
	6/12	26	
	7/14	28	
		30	

9. TUMOR STENT

FAMILY	SIZE (FR)	LENGTH (CM)	TYPE
TS	5/10	24	BEO
	6/12	26	
	7/14	28	
		30	

10. DOUBLE J STENT LONG DURO

FAMILY	SIZE (x0.1 FR)	LENGTH (CM)	TYPE	COLOR	OPTIONS
DJSBES DJSOEM DJSBEM	30	12 14 16 18 20 22 24 26 28 30	OEO BEO BEC	*LD (Yellow)	/C /G /CG /S /SG /SC /SCG
	35				
	38				
	40				
	45				
	47				
	48				
	50				
	55				
	60				
	65				
70					
80					