



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 : TURP Electrode, Ball Electrode, Collings Knife, Cold Knife, Bugbee Electrode, IP Needle, Biopsy Needle & Biopsy Gun

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-03)*



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.F.J. 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	TURP Electrode	As per Rule 9 of Annex IX of MDD	Class IIb
2	Ball Electrode	As per Rule 9 of Annex IX of MDD	Class IIb
3	Collings Knife	As per Rule 9 of Annex IX of MDD	Class IIb
4	Cold Knife	As per Rule 9 of Annex IX of MDD	Class IIb
5	Bugbee Electrode	As per Rule 9 of Annex IX of MDD	Class IIb
6	IP Needle	As per Rule 6 of Annex IX of MDD	Class IIa
7	Biopsy Needle	As per Rule 6 of Annex IX of MDD	Class IIa
8	Biopsy Gun	As per Rule 6 of Annex IX of MDD	Class IIa

1. TURP ELECTRODE

FAMILY	CHANNELS	DEGREE	TYPE	
TE	24 27	30	SS DS	/S /W /O

2. BALL ELECTRODE

FAMILY	SIZE (mm)	LENGTH (CM)	TYPE	
BAE	3 5	-----	SS DS	/S /W /O

3. COLLINGS KNIFE

FAMILY	CHANNELS	LENGTH (CM)	TYPE	
CGK	24 27	-----	SS DS	/S /W /O



4. COLD KNIFE

FAMILY	CHANNELS	LENGTH (CM)	TYPE		
COK	24 27	-----	SS DS	S H	/S /W /O

5. BUGBEE ELETRODE

FAMILY	SIZE (FR.)	LENGTH (CM)	TYPE
BUE	3 4	65	-----
	5	35 65	

6. IP NEEDLE

FAMILY	SIZE (G.)	LENGTH (CM)	TYPE
IPN	16	20	2P
	18	20	
	20	15	
	20	15	Chiba
	16 18 20 22	22	3P

7. BIOPSY NEEDLE

FAMILY	SIZE (G.)	LENGTH (CM)	TYPE
BIN	18	20 25	-----
	20	20	

8. BIOPSY GUN

FAMILY	SIZE (G.)	LENGTH (CM)	TYPE
BIG	16	10 16	-----
		16	
	18	20 25	