



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 Product : Ureteral Catheter, Malecot Catheter, PCN Catheter, PCN Catheter with Needle, Suprapubic Catheter, CIC Catheter, Tiemann Catheter, Re-Entry Malecot Catheter, PCN Catheter Set, Malecot Catheter Set, Urodynamic Catheter, Amplatz Sheath, Ureteral Access Sheath

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)

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-01)*

CE CERTIFICATE NUMBER	DATE OF ISSUE	CERTIFICATE 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 Catheter	As per Rule 5 of Annex IX of MDD	Class IIa
2	Malecot Catheter	As per Rule 7 of Annex IX of MDD	Class IIa
3	PCN Catheter	As per Rule 7 of Annex IX of MDD	Class IIa
4	PCN Catheter with Needle	As per Rule 7 of Annex IX of MDD	Class IIa
5	Suprapubic Catheter	As per Rule 7 of Annex IX of MDD	Class IIa
6	CIC Catheter	As per Rule 5 of Annex IX of MDD	Class IIa
7	Tiemann Catheter	As per Rule 5 of Annex IX of MDD	Class IIa
8	Re-Entry Malecot Catheter	As per Rule 7 of Annex IX of MDD	Class IIa
9	PCN Catheter Set	As per Rule 7 of Annex IX of MDD	Class IIa
10	Malecot Catheter Set	As per Rule 7 of Annex IX of MDD	Class IIa
11	Urodynamic Catheter	As per Rule 5 of Annex IX of MDD	Class IIa
12	Amplatz Sheath	As per Rule 7 of Annex IX of MDD	Class IIa
13	Ureteral Accesss Sheath	As per Rule 7 of Annex IX of MDD	Class IIa

1. URETERAL CATHETER

Family	Size (Fr.)	Length (cm)	Type	Color/Material
UC	3 4 5 6 7	70	CLT OT AT CT WT	*PU

2. MALECOT CATHETER

Family	Size (Fr.)	Length (cm)	Type	Color/Material
MC	10 12 14 16 18 20 22 24	-----	-----	*PU



3. PCN CATHETER

Family	Size (Fr.)	Length (cm)	Type	Color/Material
PCN	6 7 8 9 10 12 14	30	-----	*PU

4. PCN CATHETER WITH NEEDLE

Family	Size (Fr.)	Length (cm)	Type	Color/Material
PCNN	08.5 10 12 14	22	-----	*PU

5. SUPRAPUBIC CATHETER

Family	Size (Fr.)	Length (cm)	Type	Color/Material
SPC	10 12 14 16 18	25	-----	*PU

6. CIC CATHETER

Family	Size (Fr.)	Length (cm)	Type	Color/Material
CIC	10 12 14 16 18	15 30	-----	-----

7. TIEMANN CATHETER

Family	Size (Fr.)	Length (cm)	Type	Color/Material
TC	10 12 14 16 18	35	-----	-----



8. RE-ENTRY MAECOTLCATHETER

Family	Size (Fr.)				Length	Type	Color/ Material
	Proxima (Fr.)	Dista Fr.)	Proxima (cm)	Dista (cm)			
REMC	10		30	15	-----	-----	*PU
	12	/5	30	26			
	14	/6	30	24			
	16	/7	26	15			
	18	/8	26	24			

9. PCN CATHETER SET: (PCN CATHETER + FD+ GW + IPN +SCALPEL)

Family	Size (Fr.)	Length (cm)	Type	Color/Material
PCNS	8	-----	-----	*PU
	10			
	12			
	14			

10. MALECOTCATHETER SET: (Malecot catheter + FD+ GW + IPN +SCALPEL)

Family	Size (Fr.)	Length (cm)	Type	Color/Material
MCS	10	30	-----	*PU
	12			
	14			
	16			
	18			
	20			
	22			
	24			

11. URO DYNAMIC CATHETER

Family	Size (Fr.)	Length (cm)	Type	Color/Material
UDC	6	40	ST PT	-----
	7	45		
		50		



12. AMPLATZ SHEATH

Family	Size (Fr.)	Length (cm)	Type	Color/Material
AS	18 20 22 24 26 28 30 32 34	17	-----	-----

13. URETERAL ACCESS SHEATH

Family	Size (Fr.)	Length (cm)	Type	Color/Material
UAS	8 10 12 14 16 18 20 22 24	-----	-----	-----