



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

Name of the Company : **MED pro Medical B.V.**

Product Name : Urology – Stents

Model/Type ref. : Refer Page 2 -Products and Models Covered in the Declaration

Address : *Vendelier 45E, 3905PC Veenendaal, Netherlands*

Notified Body : **3EC International a.s.**  
*Hranicna 18 Bratislava 82105, Slovakia*

Notified Body Number : 2265

*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, excl. 4 of MDD 93/42/EEC as amended by 2007/47/EC.*

*This declaration is based on*

a) *Harmonized Standards*

*EN ISO 13485: 2016, EN ISO 14971:2012, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-1:2006/AC:2009, EN ISO 11737-2:2009, EN ISO 11140-1:2009, EN 556-1:2001 /AC:2006, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-7:2008/AC:2009, EN ISO 10993-11:2009, EN ISO 11135-1:2007, EN ISO 10993-4:2017, EN ISO 11138-2:2017*

*Other Applicable Standards*

b) *ISO 13485: 2016, ISO 10993-10:2010, ISO 14644-1:2015, ISO 14644-2:2015, ISO 14644-9:2012, ISO 11138-1:2017, IEC 62366-1:2015/Cor 1:2016*

c) *Technical File. (QAD-TCF-UR-05)*

CE CERTIFICATE NUMBER	DATE OF ISSUE	CERTIFICATE VALIDITY
2019-MDD/QS-050	02-09-2019	26-05-2024

Place of Issue : Veenendaal

Manufacturer : MED pro Medical B.V.

Signature : 

Name : P. de Bruin

Position : Management Representative

Date : 11-09-2019



## PRODUCTS AND MODELS COVERED IN THE DECLARATION

S. No	List of Products	Model/ Type Ref.	Class	Rule#	UMDNS/ GMDN Code
1.	Guide Wire	Straight, J Tip Evergreen, Nitinol, Black & white, Zebra	II A	5	11925
2.	Double J Stent	Single Loop, Multi Loop One End Open, Both Ends Open Both Ends Closed	II A	5	16040
3.	Loop Stent	One End Open Both Ends Open	II A	5	16040
4.	Endopyelotomy Stent	Both Ends Open	II A	5	16040
5.	Tumor Stent	Both Ends Open	II A	5	16040
6.	Mono J stent	One End Open Both Ends Open	II A	5	16040
7.	Urethral Stent	---	II A	5	16040
8.	Prostate Stent	---	II A	5	16040
9.	Long Pusher for Double J Stent	---	II A	5	16040
10.	Double J Stent Long Duro	Single Loop, Multi Loop One End Open, Both Ends Open Both Ends Closed	II B	5	16040