

DECLARATION OF CONFORMITY  
ENDOLOGIX, INC.



MANUFACTURER:

ENDOLOGIX, INC, 11 STUDEBAKER, IRVINE CA 92618

MEDICAL DEVICE:

POWERLINK<sup>®</sup> SYSTEM WITH INTUITRAK DELIVERY SYSTEM<sup>®</sup>  
SEE ATTACHED LIST  
GMDN CODE 46777  
NANDO: MD0200

CLASSIFICATION - ANNEX IX:

CLASS III, PER MDD 93/42/EEC, AS AMENDED BY DIRECTIVE  
2007/47/EEC, ANNEX IX, RULE 8

CONFORMITY ASSESSMENT ROUTE:

MDD 93/42/EEC ANNEX II, CLAUSE 4

WE, THE MANUFACTURER UNDER OUR SOLE RESPONSIBILITY, HEREWITH DECLARE THAT THE STATED  
MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, OF THE PROVISIONS OF COUNCIL  
DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES;  
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC.  
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:

ISO 13485:2003/AC:2007

NOTIFIED BODY:

NSAI  
NATIONAL STANDARDS AUTHORITY OF IRELAND

IDENTIFICATION NUMBER:

 0050

(EC) CERTIFICATE(S):

252.1072



EUROPEAN REPRESENTATIVE:

EMERGO EUROPE, MOLENSTRAAT 15, 2513 BH, THE HAGUE,  
THE NETHERLANDS, TEL: +31 (0) 70 345 8570

START OF CE-MARKING:

21 MARCH 2010  
(EXPIRES 31 DECEMBER 2011)

PLACE, DATE OF DECLARATION:

IRVINE, CA, 08 DECEMBER 2010

SIGNATURE:

  
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JANET FAULS  
VP, REGULATORY AND CLINICAL AFFAIRS

**DECLARATION OF CONFORMITY  
ENDOLOGIX, INC.**

Device Family	Model No.	Delivery System Size (Fr)	Stent Graft Description				Effective Date
			Configuration	Proximal Diameter (mm)	Limb Diameter (mm)	Total Length (mm)	
Powerlink® Bifurcated Stent Graft with IntuiTrak Delivery System®	22-13-100BL	21Fr	Infrarenal	22	13	100	8/24/2010
	25-13-100BL	21Fr	Infrarenal	25	13	100	8/24/2010
	28-13-100BL	21Fr	Infrarenal	28	13	100	8/24/2010
	22-13-120BL	21Fr	Infrarenal	22	13	120	8/24/2010
	25-13-120BL	21Fr	Infrarenal	25	13	120	8/24/2010
	28-13-120BL	21Fr	Infrarenal	28	13	120	8/24/2010
	22-13-140BL	21Fr	Infrarenal	22	13	140	8/24/2010
	25-13-140BL	21Fr	Infrarenal	25	13	140	8/24/2010
	28-13-140BL	21Fr	Infrarenal	28	13	140	8/24/2010
	22-16-100BL	21Fr	Infrarenal	22	16	100	8/24/2010
	22-16-100BLs	21Fr	Infrarenal	22	16	100	8/24/2010
	25-16-100BLs	21Fr	Infrarenal	25	16	100	8/24/2010
	28-16-100BLs	21Fr	Infrarenal	28	16	100	8/24/2010
	22-16-120BLs	21Fr	Infrarenal	22	16	120	8/24/2010
	25-16-120BLs	21Fr	Infrarenal	25	16	120	8/24/2010
	28-16-120BLs	21Fr	Infrarenal	28	16	120	8/24/2010
	22-16-120BL	21Fr	Infrarenal	22	16	120	8/24/2010
	22-16-140BL	21Fr	Infrarenal	22	16	140	8/24/2010
	25-16-100BL	21Fr	Infrarenal	25	16	100	3/21/2010
	28-16-100BL	21Fr	Infrarenal	28	16	100	3/21/2010
	25-16-120BL	21Fr	Infrarenal	25	16	120	3/21/2010
	28-16-120BL	21Fr	Infrarenal	28	16	120	3/21/2010
	25-16-135BL	21Fr	Infrarenal	25	16	135	3/21/2010
	28-16-135BL	21Fr	Infrarenal	28	16	135	3/21/2010
	25-16-140BL	21Fr	Infrarenal	25	16	140	3/21/2010
	28-16-140BL	21Fr	Infrarenal	28	16	140	3/21/2010
	25-16-155BL	21Fr	Infrarenal	25	16	155	3/21/2010
	28-16-155BL	21Fr	Infrarenal	28	16	155	3/21/2010

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Device Family	Model No.	Delivery System Size (Fr)	Stent Graft Description				Effective Date
			Configuration	Proximal Diameter (mm)	Distal Diameter (mm)	Total Length (mm)	
Powerlink® Accessory Stent Graft with IntuiTrak Delivery System®	16-16-55L	17Fr	Limb Extension	16	16	55	3/21/2010
	16-16-55FL	17Fr	Limb Extension	16	16	55	3/21/2010
	16-16-88L	17Fr	Limb Extension	16	16	88	3/21/2010
	20-13-70FL	17Fr	Limb Extension	20	13	70	8/24/2010
	20-13-88FL	17Fr	Limb Extension	20	13	88	8/24/2010
	20-20-55L	17Fr	Limb Extension	20	20	55	3/21/2010
	20-20-55FL	17Fr	Limb Extension	20	20	55	3/21/2010
	20-25-55S	19Fr	Limb Extension	20	25	55	3/21/2010
	20-25-65S	19Fr	Limb Extension	20	25	65	3/21/2010
	20-25-65F	19Fr	Limb Extension	20	25	65	3/21/2010
	22-22-55L	19Fr	Infrarenal	22	22	55	8/24/2010
	22-22-75L	19Fr	Infrarenal	22	22	75	8/24/2010
	22-22-75RL	19Fr	Suprarenal	22	22	75	8/24/2010
	22-22-95RL	19Fr	Suprarenal	22	22	95	8/24/2010
	25-25-55L	19Fr	Infrarenal	25	25	55	3/21/2010
	25-25-75L	19Fr	Infrarenal	25	25	75	3/21/2010
	25-25-75RL	19Fr	Suprarenal	25	25	75	3/21/2010
	25-25-75RLE	21Fr	Suprarenal	25	25	75	3/21/2010
	25-25-95L	19Fr	Infrarenal	25	25	95	3/21/2010
	25-25-95RL	19Fr	Suprarenal	25	25	95	3/21/2010
	25-25-95RLE	21Fr	Suprarenal	25	25	95	3/21/2010
	25-25-115RL	19Fr	Suprarenal	25	25	115	3/21/2010
	25-25-115RLE	21Fr	Suprarenal	25	25	115	3/21/2010
	28-28-55L	19Fr	Infrarenal	28	28	55	3/21/2010
	28-28-75L	19Fr	Infrarenal	28	28	75	3/21/2010
	28-28-75RL	19Fr	Suprarenal	28	28	75	3/21/2010
28-28-75RLE	21Fr	Suprarenal	28	28	75	3/21/2010	

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			Configuration	Proximal Diameter (mm)	Distal Diameter (mm)	Total Length (mm)	
Powerlink® Accessory Stent Graft with IntuiTrak Delivery System®	28-28-95L	19Fr	Infrarenal	28	28	95	3/21/2010
	28-28-95RL	19Fr	Suprarenal	28	28	95	3/21/2010
	28-28-95RLE	21Fr	Suprarenal	28	28	95	3/21/2010
	28-28-115RL	19Fr	Suprarenal	28	28	115	3/21/2010
	28-28-115RLE	21Fr	Suprarenal	28	28	115	3/21/2010
	28-28-95DS	19Fr	Suprarenal	28	28	95	8/24/2010
	28-28-190DS	19Fr	Suprarenal	28	28	190	3/21/2010
	31-31-80L	21Fr	Infrarenal	31	31	80	8/24/2010
	31-31-80LE	21Fr	Infrarenal	31	31	80	8/24/2010
	31-31-100RL	21Fr	Suprarenal	31	31	100	8/24/2010
	31-31-100RLE	21Fr	Suprarenal	31	31	100	8/24/2010
	34-34-80L	21Fr	Infrarenal	34	34	80	3/21/2010
	34-34-80LE	21Fr	Infrarenal	34	34	80	3/21/2010
	34-34-100L	21Fr	Infrarenal	34	34	100	3/21/2010
	34-34-100LE	21Fr	Infrarenal	34	34	100	3/21/2010
	34-34-100RL	21Fr	Suprarenal	34	34	100	3/21/2010
	34-34-100RLE	21Fr	Suprarenal	34	34	100	3/21/2010
	34-34-100DS	19Fr	Suprarenal	34	34	100	3/21/2010
	34-34-120RL	21Fr	Suprarenal	34	34	120	3/21/2010
	34-34-120RLE	21Fr	Suprarenal	34	34	120	3/21/2010
34-34-200DS	19Fr	Suprarenal	34	34	200	3/21/2010	

Note: 'LE' denotes the IntuiTrak Express delivery system.