

DECLARATION OF CONFORMITY
ENDOLOGIX, INC.



MANUFACTURER:

ENDOLOGIX, INC, 11 STUDEBAKER, IRVINE CA 92618

MEDICAL DEVICE:

DUAL LUMEN CATHETER

MODEL: DL-35-90

GMDN CODE 17846

NANDO: MD 0100

CLASSIFICATION - ANNEX IX:

CLASS IIA, PER MDD 93/42/EEC, AS AMENDED BY DIRECTIVE
2007/47/EEC, ANNEX IX, RULE 7

CONFORMITY ASSESSMENT ROUTE:

MDD 93/42/EEC ANNEX II, CLAUSE 3

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:

CE 0050

(EC) CERTIFICATE(S):

252.1073

EC REP

EUROPEAN REPRESENTATIVE:

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

START OF CE-MARKING:

18 MARCH 2010

(EXPIRES 31 DECEMBER 2011)

PLACE, DATE OF DECLARATION:

IRVINE, CA, 16 DECEMBER 2010

SIGNATURE:

JANET FAULS

VP, REGULATORY AND CLINICAL AFFAIRS