DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
CONCERNING MEDICAL DEVICES

MANUFACTURER:	Hamilton Thorne, Inc. *100 CUMMINGS CENTER, SUITE 465E, BEVERLY MA 01915 USA*
EUROPEAN REPRESENTATIVE:	EC REP : *ADVENA LTD. PURE OFFICES, PLATO CLOSE, WARWICK CV34 6WE UK*
PRODUCT FAMILY:	ASSISTED REPRODUCTION LASER SYSTEM
DEVICE NAME:	*LYKOS*
PRODUCT TYPE:	LASERS, DIODE, IN VITRO ASSISTED REPRODUCTION
DEVICE CLASSIFICATION - *ANNEX IX*:	*CLASS IIA, RULE 9 (ALL ACTIVE THERAPEUTIC DEVICES INTENDED TO ADMINISTER OR EXCHANGE ENERGY)*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX II WITHOUT SECTION 4 MEDICAL DEVICE DIRECTIVE 93/42/EEC AS AMENDED BY 2007/47/EC*

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:	EN 61010-1:2010, EN 1041:2008, EN ISO 13485:2012, EN ISO 14971:2012, IEC 62304:2006, IEC 60825-1/A2:2014, EN 61326-1:2013, EN ISO 15223-1:2012
NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	G1 17 02 78514 004
START OF CE-MARKING:	MAY 3, 2012
PLACE OF DECLARATION:	*BEVERLY, MA*
SIGNATURE:	DIARMAID DOUGLAS-HAMILTON *C.T.O. & S.V.P. OF R&D*