

**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:



: 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

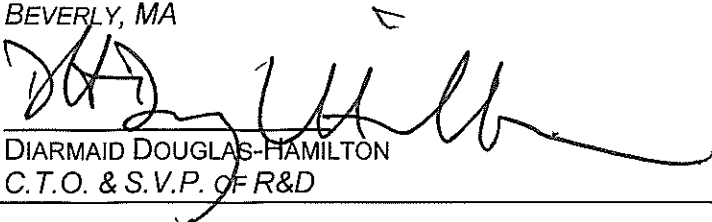
START OF CE-MARKING:

MAY 3, 2012

PLACE OF DECLARATION:

BEVERLY, MA

SIGNATURE:


DIARMAID DOUGLAS-HAMILTON
C.T.O. & S.V.P. OF R&D