BIODEX
Biodex Medical Systems, Inc.
20 Ramsey Road, Shirley, New York, 11967-4704

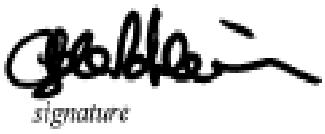
DECLARATION OF CONFORMITY

APPLICATION OF COUNCIL DIRECTIVE(s) AND NATIONAL REGULATION OF SWEDEN	93/42/EEC as amended by 2007/47/EC : LVFS 2003:11
DATE OF ISSUE	**November 28, 2017**
TYPE OF EQUIPMENT	Thyroid Uptake Probe
BRANDNAME	Atomlab 960 Thyroid Uptake System
MODEL NUMBER(s)	187-600, 187-601, 187-602
SERIAL NUMBER	**SAMPLE**
STANDARD(s) TO WHICH CONFORMITY IS DECLARED	IEC 60601-1-6 3rd Ed. IEC 60601-1-6 2nd Ed. CAN/CSA C22.2 No.601-1M90 2nd Ed. IEC 60601-1-6 ANSI 60601-1 3rd Ed. IEC 60601-1 3rd Ed. IEC 60601-1 2nd Ed. UL 60601-1 (2003) IEC 62366:2007 EMC Retlif R-14213 (includes the following): Conforms to the emissions requirements of EN60601-1-2:2007/AC:2010 CISPR 11 Edition 5.1:2010-05 Conducted Emissions, Group 1, Class A CISPR 11 Edition 5.1:2010-05 Radiated Emissions, Group 1, Class A IEC 61000-3-2 Edition 3.2: 2009 Harmonics IEC 61000-3-3 Edition 2.0: 2008-06 Flicker Conforms to the immunity requirements of EN60601-1-2:2007/AC:2010: IEC 61000-4-2 Edition 2.0: 2008-12 Electrostatic Discharge IEC 61000-4-3 Edition 3.2: 2010-04 Radiated Immunity IEC 61000-4-4 Edition 2.1: 2011-03 EFT/Burst, Power Leads IEC 61000-4-5 Edition 2.0: 2005-11 Surge Immunity, Power Leads IEC 61000-4-6 Edition 2.0: 2003, A1:2004, A2:2006 Conducted Immunity, Power & I/O Leads IEC 61000-4-8 Edition 2.0:2009-09 Power Frequency Magnetic Fields IEC 61000-4-11 Edition 2.0:2004-03(Int. sheet 1) Voltage Dips and Interrupts
BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM	ISO 13485:2003 Certificate #98-1091h-03 ISO 9001:2008 Certificate #9060-5-03
CLASS	IIa Annex II
NOTIFIED BODY	Intertek Semko AB Torshamnsgatan 43 Box 1103 SE-164 22 Kista, Sweden
E.C. CERTIFICATE #	41313009
CE IDENTIFICATION #	0413

ISSUED BY MANUFACTURER:

Biodex Medical Systems, Inc., 20 Rsmsey Road, Shirley, New York 11967-4704 USA
I, the undersigned, hereby declare that the equipment specified above conforms to the Directive(s) and Standard(s) as specified.

Authorized European Representative



Clyde Schlein
Vice President, Regulatory Affairs & Compliance

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