


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	Radionuclide Dose Calibrators
BRANDNAME	Atomlab 500
MODEL NUMBER(s)	086-330, 086-331, 086-332, 086-336
SERIAL NUMBER	SAMPLE
TYPE OF EQUIPMENT	Radionuclide Dose Calibrators
BRANDNAME	Atomlab 400
MODEL NUMBER(s)	086-335
SERIAL NUMBER	SAMPLE
TYPE OF EQUIPMENT	Radionuclide Dose Calibrator Accessories & Replacement Parts
BRANDNAME	Atomlab
MODEL NUMBER(s)	008-015, 075-596, 086-241, 086-242, 086-243, 086-338, 086-423, 086-435, 086-509
STANDARD(s) TO WHICH CONFORMITY IS DECLARED	EN 60601-1 Ed 3 EN 60601-1-2 2007 UL 60601-1: 2003 CAN/CSA C22.2 No.:601-1-M90
BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM	ISO 9001:2008 Certificate #98-1091h-03 ISO 13485:2003 Certificate #9060-5-03
CLASS	I Measuring Annex V
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES
E.C. CERTIFICATE #	41312458
CE IDENTIFICATION #	0413 
ISSUED BY MANUFACTURER: Biodex Medical Systems, Inc. 20 Ramsey 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



signature

Clyde Schlein
Vice President, Regulatory Affairs & Compliance



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