BIODEX

DECLARATION OF CONFORMITY

PRODUCT INDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
Multi-Channel Analyzer	Atomlab 960 Thyroid Uptake System	187-600, 187-601, 187-602
Serial Number	N/A	

MANUFACTURER

Name of Company	Address	Representative
Biodex Medical Systems, Inc.	20 Ramsey Road Shirley, NY 11967-4704 USA	Clyde Schlein *Vice President, Regulatory Affairs & Compliance*

AUTHORIZED REPRESENTATIVE

Name of Company	Address	Telephone/Email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	Phone: +31.70.345.8570 Fax: +31.70.346.8570

REGISTRATION INFORMATION

Notified Body and ID#	CE Certificate No & Expiration Date		Date CE Marking First Applied
Intertek Services	41313009-01	July 20, 2023	N/A

CONFORMITY ASSESSMENT

Device Classification	Route to Compliance	Standards Application
Class IIa Rule 10	Annex II of MDD 93/42/EEC Council Directive	AAMI ES 60601-1 3rd Ed CAN/CSA C22.2#60601-1:2008(Ed.2+C2) IEC 60601-1-6, 3rd Ed IEC 60601-1, 3rd Ed IEC 62366:2007, 1st Ed EMC Retlif R-16711 Rev A (includes the following): Conforms to the emissions requirements of IEC60601-1-2:2014 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 3.2:2009Harmonics IEC 61000-3-3 Edition 3.0: 2013 Flicker Conforms to the immunity requirements of IEC60601-1-2:2014 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 3.0:2012-04 EFT/Burst, Power Ports IEC 61000-4-5 Edition 2.0: 2005-11 Surge Immunity, Power Leads IEC 61000-4-6 Edition 4.0:2013-10 Conducted Immunity, Power & I/O Ports IEC 61000-4-8 Edition 2.0:2009-09 Power Frequency Magnetic Fields IEC 61000-4-11 Edition 2.0:2004-03 Voltage Dips and Interrupts

QUALITY SYSTEM REGISTRAR

Intertek Services	Certified Quality Management System: ISO 13485:2016 Certificate: 0084059

Biodex Medical Systems, Inc. declares the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices.

Company Representative: Clyde Schlein
Title: Vice President, Regulatory Affairs & Compliance
Date: May 1, 2019

No. 078 Rev. C

Signature: 

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