BIODEX

DECLARATION OF CONFORMITY

PRODUCT INDENTIFICATION		
Type of Equipment	**Product Name(s)**	**Model/Number(s)**
Radionuclide Dose Calibrators	Atomlab 500	086-330/-331/-332/-336

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	41312458-01 7-20-2023	N/A

CONFORMITY ASSESSMENT		
Device Classification	**Route to Compliance**	**Standards Application**
Class I Measuring Rule #12 Annex V	Annex V of MDD 93/42/EEC Council Directive	EN60601-1 Ed3 EN 60601-1-2:2007 IEC 60601-1-1:2000 Ed 2 IEC 601-1:1988 +A1 +A2 UL 60601-1:2003 CAN/CSA c22.2 No.:601-1-M90 IEC 60601-1-4:2000

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. 135 Rev. G

Signature: 

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