

BIODEX

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
Ultrasound Tables, AC Powered	Echo Pro Echocardiography Table	058-700, 058-705
	Echo/Vasc Pro Vascular Table	058-702, 058-707
	Econo Echocardiography Table	058-701, 058-706
	Econo Ultrasound Table	058-726, 058-727
	Sound Pro Combination Table	058-710, 058-715
	Ultra Pro Ultrasound Table	058-720, 058-725
	Vasc Pro Vascular Ultrasound Table	058-732, 058-733

Serial Number N/A

MANUFACTURER

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

CONFORMITY ASSESSMENT

Device Classification	Route to Compliance	Standards Application
Non CE	Annex VII of MDD 93/42/EEC	EN 60601-1, 2 nd Ed, 1990+A1+A2
Class I	Council Directive	EN 60601-1:1998
Rule 12		EN 61000-6-1
		EN 61000-6-2
		EN 61000-6-3
		EN 61000-6-4
		EN 60601-1-2
		EN 1970
		UL 60601-1, 1 st Ed, 2003/4/25 rev 2006/05/26
		CAN/CSA C22.2 No.:601,1M9, 1990/01/11(R2005)

QUALITY SYSTEM REGISTRAR

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

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

No. 139 Rev. A

Signature:



Biodex Medical Systems, Inc.

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