

BIODEX

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
C-Arm Radiologic Table	Urology C-Arm Table-800	058-800, 058-805
	Brachytherapy C-Arm Table-810	058-810, 058-815
	3D Imaging C-Arm Table-820	058-820, 058-825
	Surgical C-Arm Table-840	058-840, 058-840-10 058-845, 058-845-10
	Surgical C-Arm Table-846	058-846, 058-846-10 058-847, 058-847-10
	Pain Management C-Arm Table –870	058-870, 058-870-10 058-875, 058-875-10

Serial Number

[ENTER]

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>

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

CONFORMITY ASSESSMENT

Device Classification	Route to Compliance	Standards Application
Class I Rule 12	Annex VII of MDD 93/42/EEC Council Directive	EN 60601-1: 1990+A1+A2 EN 60601-1-2:2001, 2 ND Ed, rev 2 CISPR 22 Conducted: 1997 CISP 11 radiated: 1997 UL 60601-1:2002 2 nd Ed, rev 2006/04/26

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.

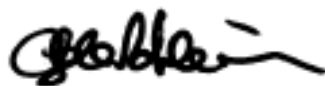
Company Representative: Clyde Schlein

Title: Vice President, Regulatory Affairs & Compliance

Date: May 1, 2019

No. 043 Rev. A

Signature:



Biodex Medical Systems, Inc.

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