BIODEX

DECLARATION OF CONFORMITY

PRODUCT INDENTIFICATION		
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 *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

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, 2ND Ed, rev 2 CISPR 22 Conducted: 1997 CISP 11 radiated: 1997 UL 60601-1:2002 2nd 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: