BIODEX
Part of Mirion Technologies

www.biodex.com

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Biodex Medical Systems, Inc.	20 Ramsey Road Shirley, NY 11967-4704 USA	TBD

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Phone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	**Code / Catalog Number**
Table, Urology C-Arm-800,115VAC	058-800
Table, Urology C-Arm-800, 230 VAC	058-805
Table, Brachytherapy C-Arm, 115 VAC	058-810
Table, Brachytherapy C-Arm, 230 VAC	058-815
Table, 3-D Imaging C-Arm, 115 VAC	058-820
Table, 3D Imaging, C-Arm, 230 VAC	058-825
Table, Surgical C-arm, Contour 115VAC	058-840
Table, Surgical C-arm, Rectangle top, 115VAC	058-840-10
Table, Surgical C-Arm, 230 VAC	058-845
Table, Surgical C-Arm, Rectangle Top, 230 VAC	058-845-10
Table, Surgical C-Arm, Contour, 115 VAC	058-846
Table, Surgical C-Arm, Rectangle, 115 VAC	058-846-10
Table, Surgical C-Arm, Contour, 230 VAC	058-847
Table, Surgical C-Arm, Rectangle, 30 VAC	058-847-10
Table, Pain Management C-Arm, 115VAC	058-870
Table, Pain Management C-Arm, Rectangular Top, 115VAC	058-870-10
Table, Pain Management C-Arm, 230VAC	058-875
Table, Pain Management C-Arm, Rectangular Top, 230VAC	058-875-10
Intended Purpose	**Basic UDI-DI**
For medical purposes to support a patient during image-guided procedures as well as in cardiovascular, vascular, pain care, urology, genealogical, brachytherapy procedures.	07181751014M

Biodex Medical Systems, Inc.
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RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	I	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 ANSI/AAMI ES60601-1:2005 + A1:2012 + C1:2009 and A2:2010 CAN/CSA-C22.2 No. 60601-1:2014 IEC 60601-2-46 Edition 3.0 CAN/CSA-22.2 No. 60601-2-46:12 IEC 60601-1-2:2014
Rule:	13	

Biodex Medical Systems, Inc. declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745
- RoHs Directive: RoHs 2011/65/EU
- Machinery Directive 2006-42-EC EHSR Report

COMPANY REPRESENTATIVE: Paul Cadmus
TITLE: General Manager, Senior Vice President Operations
SIGNATURE:

DATE: 28/04/2021
PLACE: Biodex Medical Systems, Inc.
20 Ramsey Road
Shirley, NY 11967-4704, USA