

BIODEX

Biodex Medical Systems, Inc.
20 Ramsey Road, Shirley, New York, 11967-4704

DECLARATION OF CONFORMITY

APPLICATION OF COUNCIL DIRECTIVE(S) AND NATIONAL REGULATION OF SWEDEN	93/42/EEC as amended by 2007/47/EC : LVFS 2003:11			
DATE OF ISSUE	September 25, 2018			
TYPE OF EQUIPMENT	C-Arm Radiologic Table			
BRANDNAME(S) & MODEL NUMBER(S)	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	SAMPLE			
TYPE OF EQUIPMENT	C-Arm Table			
BRANDNAME	Fixed Height Table			
MODEL NUMBER	056-025			
SERIAL NUMBER	SAMPLE			
BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM				
ISO 13485:2003 CERTIFICATE #9060-5-03				
CLASS	I Annex VII			
STANDARD(S) TO WHICH CONFORMITY IS DECLARED	EN 6060101: 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 Ed, rev 2006/04/26			
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES			
AUTHORIZED EUROPEAN REPRESENTATIVE	<table border="1"> <tr> <td style="text-align: center; width: 40px; height: 40px;">EC</td> <td style="text-align: center; width: 40px; height: 40px;">REP</td> <td style="padding-left: 10px;"> EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands </td> </tr> </table>	EC	REP	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands
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ISSUED BY MANUFACTURER:

Biodex Medical Systems, Inc.
20 Ramsey Road
Shirley, New York 11967-4704 USA

I, the undersigned, hereby declare that the equipment specified above conforms to the Directive(s) and Standard(s) as specified.



signature

Clyde Schlein - Vice President, Regulatory Affairs & Compliance

#CD-CC-043