

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	Personnel Radiation Shield			
BRANDNAME(s) & MODEL NUMBER(s)	Deluxe L-Block Shield 042-413 Compact L-Block with Dose Calibrator Shield 042-433 L-Block Shields 042-419, 042-449 L-Block Caves & Accessories 042-417, 042-425, 042-426, 042-434, 042-435			
TYPE OF EQUIPMENT	Personnel Radiation Shield			
BRANDNAME(s) & MODEL NUMBER(s)	Tabletop Shield 042-224, 042-710 Tabletop Shield Accessories 042-226, 042-227, 042-228			
BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM ISO 13485:2003 CERTIFICATE #9060-5-03				
CLASS	I Annex VII			
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES			
AUTHORIZED EUROPEAN REPRESENTATIVE	<table border="1"> <tr> <td style="text-align: center; vertical-align: middle;">EC</td> <td style="text-align: center; vertical-align: middle;">REP</td> <td> 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-124 rev E