

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	Shielded Injection Stand			
BRANDNAME	Injection Stand			
MODEL NUMBER(s)	135-022			
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" style="border-collapse: collapse;"> <tr> <td style="text-align: center; width: 40px;">EC</td> <td style="text-align: center; width: 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-121 rev D