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 **BRANDNAME** **MODEL NUMBER(s)**	**RADIATION SYRINGE SHIELDS** **PRO-TEC II:** 007-800, 007-801, 007-900, 007-901 **PRO-TEC III:** 007-723, 007-734, 007-735 007-736, 007-738, 007-755 **PRO-TEC IV:** 007-670, 007-675, 007-680, 007-685 **BETA:** 007-956, 007-957 **DOSE DRAWING:** 007-661, 007-663, 007-665 007-691, 007-693, 007-695 **DOUBLE-ENDED PET PIG:** 001-793 **HIGH DENSITY LEAD GLASS:** 007-612, 007-620, 007-635, 007-652 **PET:** 007-973, 007-975, 007-980, 007-983, 007-985, 007-990, 007-995 **PET/MR:** 007-961, 007-962, 007-966, 007-967 **PET GAARD LOCK:** 007-711, 007-712, 007-713 007-716, 007-717, 007-718 **Z-PET:** 007-945 **REPLACEMENT GLASS:** 007-974, 127-691, 127-693, 127-695, 127-700 127-734, 127-735, 127-738, 127-789, 127-999
TYPE OF EQUIPMENT **BRANDNAME** **MODEL NUMBER(s)**	**SYRINGE CARRIER** Biodex 001-179, 001-180, 001-181, 001-182
BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM ISO 13485:2003 CERTIFICATE #9060-5-03	
CLASS	I Annex VII
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES

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

Authorized European Representative:

EC REP
EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Clyde Schlein,
Vice President, Regulatory Affairs & Compliance

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