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	Radionuclide Rebreathing System
BRANDNAME	Venti-Scan IV
MODEL NUMBER(s)	**Venti-Scan IV Shield with IV Mount:** 177-090 **Venti Pak Adapter:** 177-075 **Venti-Scan IV Convenience Kit:** 177-091, 177-092
BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM ISO 13485:2003 CERTIFICATE #9060-5-03	
STANDARD(s) TO WHICH CONFORMITY IS DECLARED	EN 60601-1: 1988
CLASS	I Annex VII
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES
AUTHORIZED EUROPEAN REPRESENTATIVE	EC REP EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands

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.

Clyde Schlein
Vice President, Regulatory Affairs & Compliance

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