

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	November 28, 2017			
TYPE OF EQUIPMENT	Nebulizer (for direct patient interface)			
BRANDNAME	Micro-Vent Kit, Disposable			
MODEL NUMBER(S)	177-107			
BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM ISO 9001:2008 CERTIFICATE #98-1091h-03 ISO 13485:2003 CERTIFICATE #9060-5-03				
CLASS	I Annex VII			
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES			
AUTHORIZED EUROPEAN REPRESENTATIVE	<table border="1"><tr><td>EC</td><td>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-100 rev L