

BIODEX

Biodex Medical Systems, Inc.
20 Ramsey Road, Shirley, New York, 11967-4704

April 21, 2020

To Whom It May Concern:

The Biodex Pulmonex II Xenon System, Model #132-503, is assembled according to its requirements and specifications.

The Biodex Quality System is ISO-13485:2016 Certified.

The Pulmonex Xenon System complies with Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012(or IEC 60601-1: 2012 reprint), (R2012) [AAMI ES60601-1:2005 + A1 + C1;A2], [CSA C22.2#60601-1:2014 Ed.3], [IEC 60601-1-6:2010 Ed.3+A1], [IEC 62366:2007 Ed.1+A1], IEC 60601-1-2 Ed 4.0 (2014-02).

Sincerely,

A handwritten signature in black ink, appearing to read "Paul Cadmus", with a long horizontal line extending to the right.

Paul Cadmus
Acting Vice President Regulatory Affairs & Compliance