



EU Declaration of Conformity

For the following equipment:

AC-DC Internal Power Supply
Bear Power Supplies: BPX20YYZZ0
Where: X is Series (1,3,4,6,7)
YY is Output Wattage (05,10,15,30)
ZZ is Output Voltage (05,12,15,24)

Manufacturer:
Z-Axis, Inc
1916 Route 96
Phelps, NY 14532

This declaration of conformity is issued under the sole responsibility of the manufacturer.

The devices described above are in conformity with the following relevant Union harmonization legislation:

Medical Device Regulation (EU) 2017/745, Class I

Low Voltage Directive 2014/35/EU

EMC Directive 2014/30/EU

RoHS Directive 2011/65/EU & (EU) 2015/863

The conformity to these directives references the following standards and technical documentation in which the devices were tested to:

IEC 60601-1:2005/A1:2012

EN 60601-1:2006/A1:2013

ANSI/AMII ES60601-1:2005/(R)2012 and A1:2012

CSA-C22.2 No. 60601-1:2014

IEC 55011 (CISPR11), A1:2010

IEC 55011 (CISPR11) 2015 +A1:2016+A2:2019

IEC 61000-3-2, 2005 +A1:2008 +A2:2009 + 2018 +A1:2020

IEC 61000-3-3, 2013-05+ 2017-05-18

IEC 61000-4-2, 2008-12

IEC 61000-4-3, A1:2007+A2:2010

IEC 61000-4-4, 2012-04



BEAR
POWER SUPPLIES

IEC 61000-4-5, 2005+ 2017-08-04

IEC 61000-4-6, 2003 +A1:2004+A2:2006+2013

IEC 61000-4-8, 2009-09

EN 61000-4-11, 2004-03 + 2020-01- 28

IEC 60601-1-2, 2014-02

IEC 60601-1-2, 2007

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Bear Power Supplies
Date of Issue: January 18, 2023