

Technical Report No.: 090-72173557-000

Date: 2022-08-24

Client: Z-Axis Inc (# 24500)
1916 Route 96
Phelps, NY 14532, USA

Manufacturer: Z-Axis Inc (# 24500)
1916 Route 96
Phelps, NY 14532, USA

Factory: Z-Axis Inc (# 24500)
1916 Route 96
Phelps, NY 14532, USA

Product: Medical AC to DC Power Supply

Test object: BPX20YYZZ0

Model: X is series (can be 1, 3, 4, 6, 7)
YY is wattage (can be 05, 10, 15, or 30W)
ZZ is voltage (can be 05, 12, 15, or 24V)

Test specification: 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

The Risk Management requirements of the standard were not addressed, excluding Clauses 7.5, 7.9 and 10

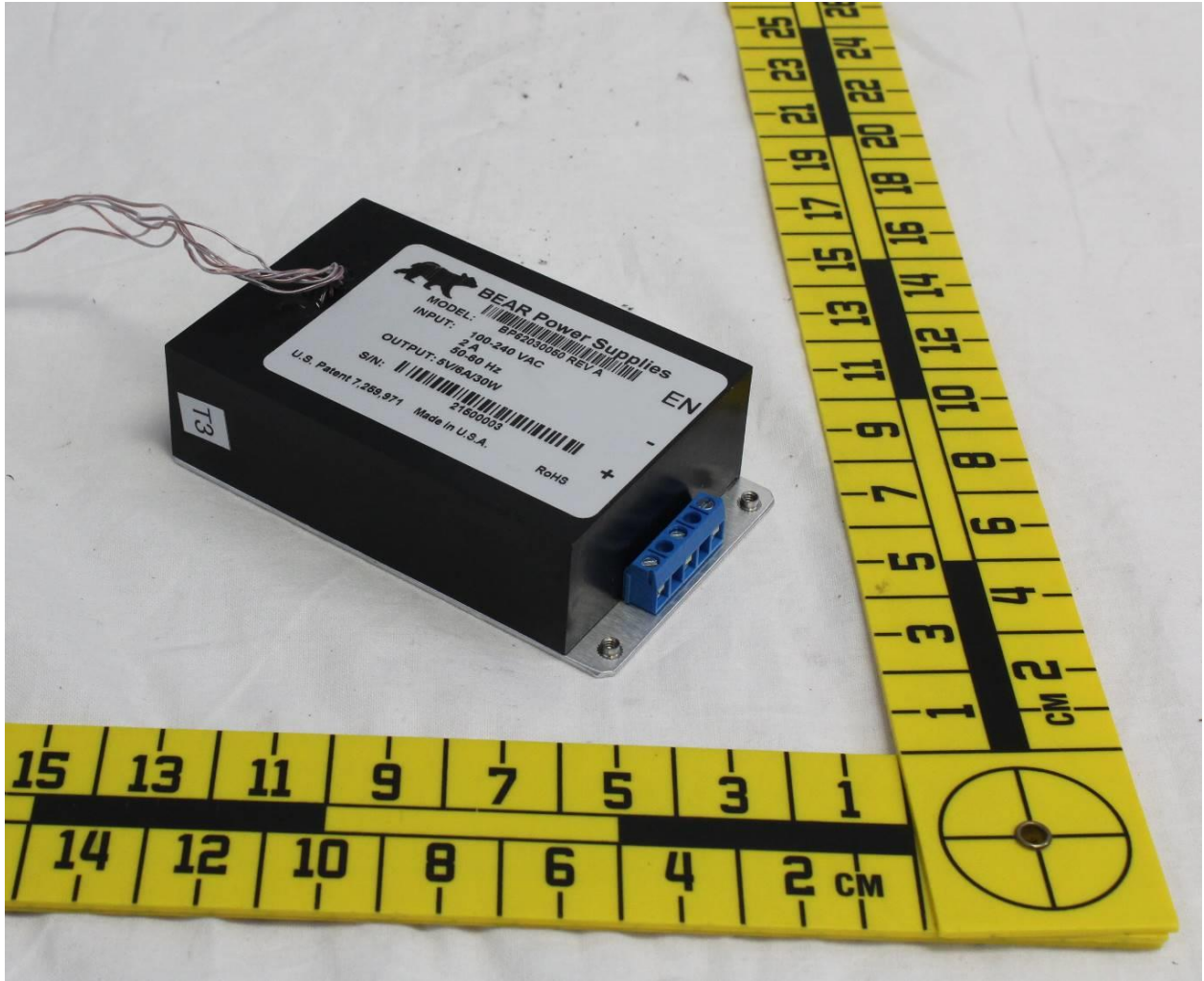
Purpose of examination: • According to the test specification.

Test result: The test results show that the presented product is in compliance with the specified requirements.

Any use for advertising purposes must be granted in writing. This technical report may only be quoted in full. This report is the result of a single examination of the object in question. It does not imply a general statement regarding the quality of products from regular production. For further details please see testing and certification regulation, chapter A-3.4.

1. Description of the test object

1.1 Picture(s)



1.2 Function

The equipment is a small, potted, off-the-shelf power supply for medical and industrial uses.

Manufacturer's specification for intended use:
According to the user manual

Manufacturer's specification for predictive use:
According to the user manual

1.3 Consideration of the foreseeable use

- Not applicable
- Covered through the applied standard
- Covered by the following comment*
- Covered by attached risk analysis

1.4 Technical Data

Input: 100-240VAC 2-0.1A 50-60Hz
Output: 5, 12, 15 or 24Vdc
5, 10, 15 or 30W

2. Order

2.1 Date of Purchase Order, Customer's Reference

2021-10-11, PO# PO135068, TUV Reference 72173557

2.2 Test Sample(s)

- Reception date(s): 2021-12-02
- Location(s) of reception: TUV SUD America, 10 Technology Drive, Peabody, MA 01960
- Condition of test sample(s): Functional

2.3 Date(s) of Testing 2022-01-10 through 2022-05-26

2.4 Location(s) of Testing TUV SUD America, 10 Technology Drive, Peabody, MA 01960

2.5 Points of Non-Compliance or Exceptions of the Test Procedure

- None

3. Test Results

Positive

3.1 Positive Test Results

Test specification(s)	Report no. / Rev. No.	Date	Remark
Electrical safety: 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	090-72173557-000	2022-08-24	Pass
Mechanical safety: 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	090-72173557-000	2022-08-24	Pass

3.2 Points of Non-Compliance according to the test specification

None

4. Remarks

4.1 General

The user specification document has been examined according to the minimum requirements described in the product standard. The manufacturer is responsible for the accuracy of further particulars as well as of the composition and layout.

4.2 Factory surveillance cycle

Your production facility is currently on a

- Annual (12 month)
- Bi-Annual (6 month)
- Quarterly (3 month)
-

surveillance cycle.

5. Documentation

File	File name	Date
Test Report Form:	090-72173557-000_TRF	2022-08-24

6. Summary

The test specification is met

TÜV SÜD America Inc.

Tested by:

Wendell Harvey
MHS Test Engineer
printed name, function & signature



Approved by:

Ed Gaff
MHS Test Engineer
printed name, function & signature

