UL TEST REPORT AND PROCEDURE

Standard:	AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021 CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental - Component)
Complementary CCN:	N/A
Product:	Power Supply
Model:	mFZP-075-5x, mFZP-075-12x, mFZP-075-15x, mFZP-075-24x (where x maybe maximum 20 characters, any alphanumeric character, hyphen, slash or blank)
Rating:	Model mFZP-075-5x: Input: 100-240 Vac, 50-60 Hz, 1.2-0.8 A Output: 5 Vdc, 10 A (Peak 15 A) Model mFZP-075-12x: Input: 100-240 Vac, 50-60 Hz, 1.5-0.9 A Output: 12 Vdc, 6.25 A (Peak 12.5 A) Model mFZP-075-15x: Input: 100-240 Vac, 50-60 Hz, 1.5-0.9 A Output: 15 Vdc, 5 A (Peak 10 A) Model mFZP-075-24x: Input: 100-240 Vac, 50-60 Hz, 1.5-0.9 A Output: 24 Vdc, 3.13 A (Peak 6.25 A)
Applicant Name and Address:	NIPRON CO LTD 2-57 OHAMA-CHO AMAGASAKI-SHI HYOGO 660-0095 JAPAN

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared By:	Yoshifusa Koyanagi / Project Handler	Reviewed By:	Deborah Jennings-Conner / Reviewer

Supporting Documentation

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

A. Authorization - The Authorization page may include additional Factory Identification Code markings.

B. Generic Inspection Instructions -

i. Part AC details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.

ii. Part AE details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.

iii. Part AF details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

Product Description

The equipment under tests is power supply intended to be built into end-product installations.

The equipment has the following option.

- Capacitor board, type CB03*. CN1 of this unit is connected to CN3 (optional) of the power supply by harness.

Model Differences

Model mFZP-075-24x is the basic model described in this report.

Models mFZP-075-12x and mFZP-075-15x are identical to Model mFZP-075-24x except for output rating, constant of some minor components, and model designation and winding of Transformer (T1).

Model mFZP-075-5x is identical to Model mFZP-075-24x except for input/output rating, constant of some minor components, derating curve, and model designation and winding of Transformer (T1).

Suffixes x denote control numbers which do not affect safety. (Where x maybe maximum 20 characters, any alphanumeric character, hyphen, slash or blank)

Unless otherwise specified, Model mFZP-075-24x was tested as a representative of entire series.

Test Item Particulars

Classification of installation and use ..... :	Built-in
Supply Connection ..... :	N/A (to be considered in end-use product)
Device type (component/sub-assembly/ equipment/ system) ..... :	Component
Intended use (Including type of patient, application location) ..... :	To supply regulated power, no patient connection
Mode of operation ..... :	Continuous
Accessories and detachable parts included ..... :	None
Other options include ..... :	Chassis, cover, capacitor board (type CB03* (* maybe maximum 20 characters, any alphanumeric character, "-" or "/" or blank, which denotes control number))

Technical Considerations

- The product was investigated to the following additional standards : EN 60601-1:2006 + A1:2013 + A12:2014 + A2:2021
- The following additional investigations were conducted : N/A
- The product was NOT investigated to the following standards or clauses : Biocompatibility, Risk Assessment, EMC, Annex Z of EN standards for compliance with the MDD
- The following accessories were investigated for use with the product : Chassis, cover, capacitor board (type CB03*)
- For some of critical components, EN standards were used to verify the compliance. The EN standards were harmonized to IEC standard, and technically equivalent.
  When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.
  The product is not suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide.
  Input voltage deviation is -15 %, +10%. See Enclosure ID 07-01 for derating curve and mounting orientation.

Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by UL LLC. When installed in an end-product, consideration must be given to the following:

- The equipment is not provided with disconnecting means in accordance with cl. 8.11.1. It shall be considered in the end product.
- The output circuit has not been evaluated for direct patient connection (type B, BF or CF). Additional requirements may be required if used for connection to applied parts.
- The following the end product enclosures are required: Electrical, Fire.
- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the equipment is used with the end product. The end product shall ensure that the equipment is used within its ratings.
- Instructions for use shall be checked in the end product.
- The equipment has been evaluated for use under pollution degree 2, overvoltage category II, and at altitude up to 2000 m.
- Temperature Test was conducted without test corner. The acceptability of risk in conjunction to temperature testing with test corner shall be considered in the end product.
- Proper bonding to protective earthing terminal of the end product shall be provided.
- Input and output connectors are not intended for field-wiring connection. They are only intended for factory-wiring inside the end product.
- Final installation of this equipment should comply with the enclosure, mounting, marking, spacing and separation requirements. In addition, temperature, leakage current, dielectric voltage withstand and interruption of this equipment tests should be considered as part of the end product evaluation.
- Risk management process in accordance with cl. 4.2 shall be evaluated in the end product.
- The equipment has been judged on the basis of the required creepage and clearance according to cl. 8.9 in IEC 60601-1 edition 3.2 (2020) that covers the end application for which the component was designed.
- The equipment has been evaluated as class I, continuous operation, and not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. Additional evaluations shall be considered if the equipment is intended for classifications other than these.
- The following magnetic devices (e.g. transformers or inductor) are provided with an OBJY2 insulation system with the indicated rating greater than Class A (105 °C): Transformer (T1) (class B).
- The equipment provides 1MOOP/1MOPP between primary and GND, and 2MOOP/2MOPP between primary and secondary circuits.
- The maximum working voltages to consider when conducting dielectric strength test are 282 Vrms, 636 Vpeak.
- Secondary output is non-hazardous voltage in accordance with cl. 8.4.2 c) except for SIP/SOP connectors and separate power supply output connectors.
- Secondary output has not been evaluated for non-hazardous energy level in accordance with cl. 8.4.2 c).
- The clearances and creepage distances between each unit shall be re-evaluated in the end product when the optional capacitor board, type CB03* is provided.
- Different polarity before F1, F2 shall be evaluated in the end product. Different polarity after F1, F2 was evaluated in abnormal test.
- Limitation of Voltage, Current or Power (8.4.2 c) for SIP/SOP connectors or separate power supply output connectors should be evaluated in end-product.

Additional Information

Maximum Normal Load Condition and mounting orientation (Test Conditions): Enclosure ID 07-01 for details. Regarding forced air cooling condition, test was conducted at using test jig provided from the applicant, which is employing DC fan, Type 109R0812T4H12 manufactured by Sanyo Denki Co., Ltd.

The marking plate label provided is representative of all series models because the required information except for model name is same as representative.

(For CB only)

This report is based on CB Test Certificate No. US-38321-UL, CB Test Report Ref. Nos. E358786-D1008-1/A0/C0-CB and E358786-D1008-1/A0/C1-CB for upgrading IEC 60601-1:2005 + A1:2012 to IEC 60601-1:2005 + A1:2012 + A2:2020.

In addition to the above, following report modifications were made from previous report:
- Addition of alternate Optical Isolators (PC1, PC2), Type LTV-10XX.
- Minor correction of table 8.10 not affecting safety.

No additional testing is considered necessary for issuing this report based on a gap analysis between the standards mentioned above and previously conducted testing.

Additional Standards

The product fulfills the requirements of: CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14, AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021

Additional country information: EU Group Differences (No National or Group Differences declared).

Markings and Instructions

Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Model	Model number

Special Instructions to UL Representative

N/A

	Product-Line Testing Requirements		
Required? (NOTE TO USER: A YES or NO verdict is required in this column.)	Test	Model/Part Exempt from Test	Additional Details
No	Grounding Continuity	N/A	N/A
Yes	Dielectric Strength	N/A	N/A
No	Patient Circuit Dielectric Voltage Withstand	N/A	N/A

	Solid State Component Instructions	
Solid State Component	Parts to be disconnected for test	Specific Test
The following solid-state components that can be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:	N/A	N/A
	N/A	N/A
	N/A	N/A
	N/A	N/A
	N/A	N/A

	Sample and Test Specifics for the Follow-Up Tests at UL		
Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
None	NA	NA	NA
N/A	N/A	N/A	N/A