CSA INTERNATIONAL

Certificate of Compliance

Certificate: 2194644 **Master Contract:** 163736

Project: 2194644 **Date Issued:** 2009-07-21

Issued to: **Astec International Ltd-Philippine Branch**
3rd and 4th Floor, Techno Plaza One Bldg
#18 Orchard Road, Eastwood City, Cyberpark
Bagumbayan
Quezon City, 1110
PHILIPPINES

Attention: Mr. Peter Paul Dychitan

The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US' for Canada and US or with adjacent indicator 'US' for US only or without either indicator for Canada only

C US

Issued by: Sanjay Chaubal

Authorized by: Jack Chin
Product Group Manager

PRODUCTS

CLASS 5311 20 - POWER SUPPLIES - Component Type-For use in Medical Equipment.
CLASS 5311 96 - POWER SUPPLIES - Component Acceptance - Certified to US Standards.

Component Type Power Supply for use with Medical Applications where the suitability of the combination is to be determined.

Model: iVS1 series.

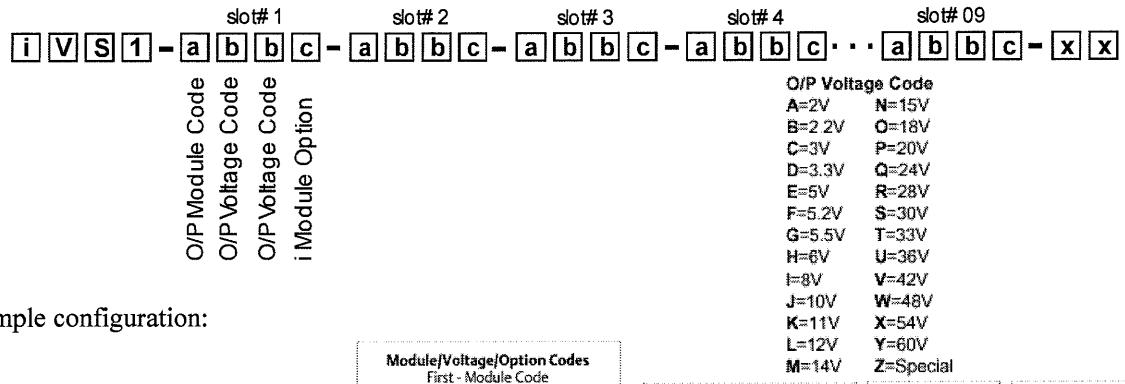
iVS1-abbc-abbc-abbc-abbc-abbc-abbc-abbc-abbc-abbc-xx where "-abbc" denotes DC-DC module version that can be used on the slots provided. The number of "-abbc" depends on the number of module slots that can be accommodated by the front-end case. Each iVS1-configured model has a total of 9 slots for the DC/DC converter modules.

iVS1 series are Class I power supplies for building-in, for use in Medical Equipment applications. It consists of the Front-end module 73-180-0001i case and DC/DC converter modules inserted on the slots provided.

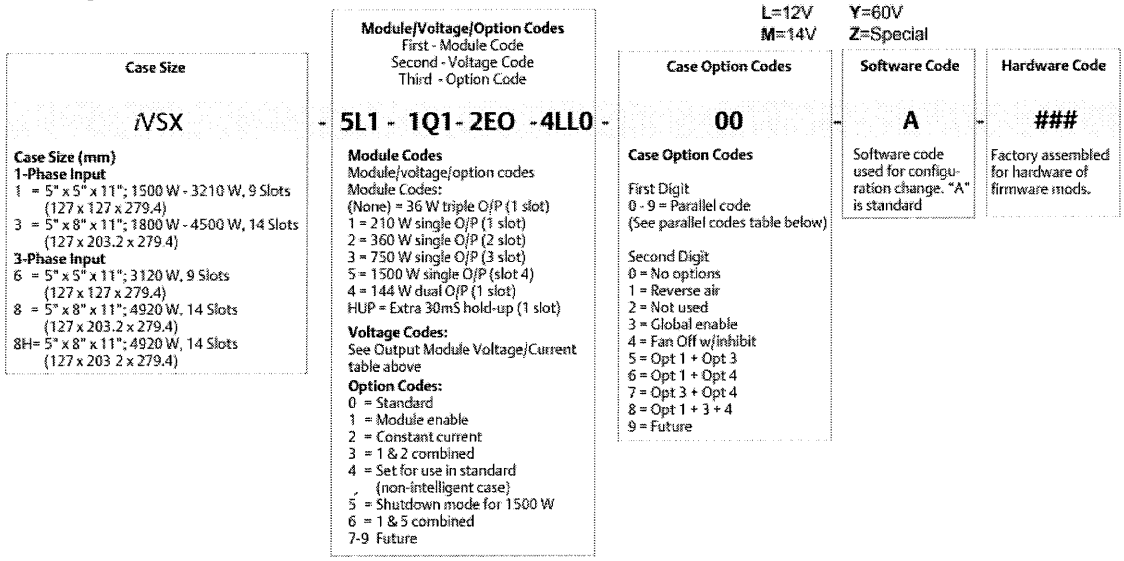
Input: AC Input: 100-120V/200-240V, 20A max., 50/60Hz
DC Input: 120V min.-170V max. / 254Vmin. – 300Vmax, 20A max.

Output ratings: Refer to the Model Configuration as follows:

Model Configuration:



Sample configuration:



Model: iVS1 series consists of the Front-end module 73-180-0001i case and DC/DC converter modules inserted on the slots provided. Each iVS1-configured model has a total of 9 slots for the DC/DC converter modules.

There are single, dual and triple output DC/DC converter modules some of which occupy more than 1 slot. The iVS1 series can be configured with various combination of the following DC/DC modules:

Single output 210W module, (width = 1 slot) : 73-551-xxxxi series
Single output 360W module, (width = 2 slots) : 73-552-xxxxi series
Single output 750W module, (width = 3 slots) : 73-553-xxxxi series
Single output 1500W module, (width = 4 slots) : 73-558-xxxxi series
Dual output 144W module, (width = 1 slot) : 73-554-xxxxi series

Triple output 36W module, (width = 1 slot) : 73-550-xxxxi series

Additional Information: These equipments are considered Class I, all equipments are with no patient applied part, not suitable for use in the presence of flammable mixtures, continuous operation and detachable cord connected.

1. Type of protection against electric shock: Class I
2. Degree of protection against electric shock: No applied part/Not Classified
3. Degree of protection against ingress of water: IPX0
4. Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
5. Mode of operation: Continuous
6. Environmental Conditions: Normal: 10-40°C, 30-75% Rh, 700-1060 hpa.

APPLICABLE REQUIREMENTS

CAN/CSA-C22.2 No. 0-M91	-	General Requirements - Canadian Electrical Code, Part II.
CAN/CSA-C22.2 No. 0.4-04	-	Bonding of Electrical Equipment.
CAN/CSA-C22.2 No. 601.1-M90	-	Medical Electrical Equipment Part I: General Requirements for Safety.
CAN/CSA-C22.2 No. 601.1S1-94	-	Supplement No. 1-94 to CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment--Part 1: General Requirements for Safety.
CAN/CSA-C22.2 No. 601.1B-98	-	Amendment 2 to CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment - Part 1: General Requirements for Safety
UL Std. No. 60601-1	-	Medical Electrical Equipment - Part 1: General Requirements for Safety.

Subject to the following qualifications:

(1) The equipment has not been investigated for the protection against hazards of explosions in medically used rooms.

(2) The equipment has been evaluated to the above standards excluding requirements for Electromagnetic Compatibility (Clause 56), Biocompatibility (Clause 48) and Programmable Electronic Systems (Clause 52.1).

(3) The main supply cord set provided with the equipment must be an approved type acceptable to the authorities where the equipment is sold.

(4) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.

(5) The power supply is not for direct patient contact or in the patient vicinity.

MARKINGS

MARKING METHOD: The markings below are made via silk screening, die stamping, moulding or on CSA certified or UL recognized adhesive nameplate material compatible with the surface used, or equivalent permanent means that can pass the label rub test under Clause 6.1.

(a) The CSA applicable mark  with optional reference to Standard CAN/CSA C22.2 No. 601.1 (AM1+AM2), UL 60601-1, or IEC 60601-1.

(b) Manufacturer's identification: Name and/or CSA file number "LR 109492" or Master Contract "163736" on the same label as the CSA Mark. The name and/or trademark should appear elsewhere on the equipment if only the file number or Master Contract is used on this label.

(c) Catalogue/Model/Type designation.

(d) Electrical rating: The complete electrical ratings (in volts, hertz and amperes) with the IEC 60417-5032 alternating current symbol ~ or letters adjacent to the marked voltage; and IEC 60417-5031 direct current symbol ⎓ or letters adjacent to the marked DC voltage.

(e) Date of manufacture: Month and year of manufacture or date code. If a serial number is used instead of date of manufacture, a record of serial numbers shall be kept traceable to date of manufacture. (Not related to date of sale).

(f) For UL 60601-1: Marking on the unit that indicates the manufacturing location if the equipment is manufactured at more than one factory location.

(g) The IEC 348 symbol  indicating "Attention: Consult Accompanying Documents".

(h) Type of protection against electrical shock: Class I for protectively grounded equipment. (May be marked on the product or recorded in accompanying documents)

(i) Degree of Protection against Harmful Ingress of Water: Ordinary equipment, IPX0. (Marking is not required if it is IPX0)

(j) Degree of Safety in the Presence of Flammable Anaesthetic Mixture with Air or Oxygen or Nitrous Oxide: Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide. (May be marked on the product or recorded in accompanying documents).

(k) Mode of Operation: Continuous.

Supplement to Certificate of Compliance

The products listed, including the latest revision described below, are eligible to be marked in accordance with the referenced Certificate.

Product Certification History

Project	Date	Description
2194644	2009-07-21	Original Certification.

Attachment to AAN for cCSAus (Med)

Date:	July 22, 2009
Product:	Switching power supply for Building-in
Standards covered:	IEC60601-1, CSA C22.2 No. 60601-1 and UL60601-1 (Medicals only)
Type designation:	**iVS1-abbc-abbc-abbc-abbc-abbc-abbc-abbc-abbc-xx (iVS1 series)**

Notes on Model name configuration:

1. if "c" is blank or not used, for example "4LF", this means the DC-DC module used is old version (non-i version). Approved application for use of such modules is for ITE 60950-1 ONLY.

2. if "c" is "4", for example "4LF4", this means the DC-DC module used is a new version (intelligent "i" version) being used for ITE60950-1 application. Approved application for use of such modules setting is for ITE 60950-1 ONLY.

3. if "c" is "0-9" except 4 as above, for example "4LF0", this means the DC-DC module used is a new version (intelligent "i" version). Approved application for use of such modules setting is for ITE 60950-1 and Medicals 60601-1.

Approved Front-end Module (case) for use in ITE or Medical application:

73-180-0001i

Approved DC-DC modules for ITE use only:

73-550-0332, 73-550-0333, 73-550-0335, and 73-550-0352
73-554-0220, 73-554-0320, 73-554-0330, 73-554-0350, 73-554-0520, and 73-554-0550
73-551-0005, 73-551-0012, 73-551-0015, 73-551-0024, and 73-551-0048
73-552-0005, 73-552-0012, 73-552-0015, 73-552-0024, and 73-552-0048
73-553-0005, 73-553-0012, 73-553-0015, 73-553-0024, and 73-553-0048

Approved DC-DC modules for ITE and Medical use:

73-550-0332i, 73-550-0333i, 73-550-0335i, and 73-550-0352i
73-554-0220i, 73-554-0320i, 73-554-0330i, 73-554-0350i, 73-554-0520i, and 73-554-0550i
73-551-0005i, 73-551-0012i, 73-551-0015i, 73-551-0024i, and 73-551-0048i
73-552-0005i, 73-552-0012i, 73-552-0015i, 73-552-0024i, and 73-552-0048i
73-553-0005i, 73-553-0012i, 73-553-0015i, 73-553-0024i, and 73-553-0048i
73-558-0012i, 73-558-0015i, 73-558-0024i and 73-558-0048i

[Note: For Medical applications, only intelligent DC-DC modules ("i"- versions) are approved for use. Non-"i" versions cannot be used for configured medical]

Approved CSA logo format to be used on label:

(per CPSS102-06)