

Guide to Product Safety

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Guide to Product Safety

In today's marketplace, not only are power supplies required to comply with functional specifications, they must meet certain performance standards such as global safety, EMC, DoE regulations, ROHS, Reach, etc. Product safety is a primary consideration of any power supply design and is necessary to market products globally. This application note is a basic overview of product safety and how it relates to power supply design and development. Much of the information covered in this document is from UL standards that are used to certify power supplies.

Purpose of Product Safety: According to UL, the safety certification is the process of assessing the compliance of products to recognized safety requirements. This certification most frequently addresses electrical safety, fire risks and other product hazards, and can include the assessment of other attributes, all focused on making products safer to use. The application of the safety standard is intended to reduce the risk of injury or damage from the following:

- **Electric Shock** – Electric shock is due to current passing through the human body.
- **Energy Related Hazards** – Injury or fire may result from a short circuit between adjacent poles of high current supplies or high capacitance circuits.
- **Fire** – Risk of fire may result from excessive temperatures either under normal operating conditions or due to overload, component failure, insulation breakdown or loose connections.
- **Heat** – Injury may result from high temperatures under normal operating conditions.
- **Mechanical** – Injury may result from contact with sharp edges or corners, moving parts, or physical instability.
- **Radiation** - Injury to users and to service persons may result from some forms of radiation emitted from equipment.
- **Chemical** – Injury may result from contact with some chemicals or from inhalation of their vapors and fumes.

SL Power solves customers concerns regarding product safety with ground up, robust design platforms that focus on safety first.

Primary Safety Standards Supported by SL Power Electronics:

IEC/EN/CSA/UL60950-1, 2nd Amendment – is the most widely applied standard for power supplies used today for Information Technology Equipment (ITE), but also for products other than non-medical applications. For example, power supplies certified to IEC/EN/CSA/UL60950-1 are accepted with additional investigation to UL8750 for LED lighting, IEC/EN/CSA/UL61010-1 for Measurement, Control and Laboratory Equipment and for Test & Measurement.

IEC/EN/CSA/ANSI/AAMI ES60601-1, 3rd Edition, Amendment 1

Definition: To govern the design of medical equipment, the International Electro technical Committee (IEC) has produced a standard to control all aspects of safety directly or indirectly relating to the handling, use or connection to, of medical equipment. This standard is referenced as IEC 60601, or simply referred to as IEC 601.

■ Patient Applied Part:

- Type B (Body) applied part - Not suitable for direct cardiac applications.
- Type BF (Body Floating) applied part - Higher degree of protection, not suitable for direct cardiac applications.
- Type CF (Cardiac Floating) applied part - Highest degree of protection, suitable for direct cardiac applications.



■ AC Leakage Current – Output to Earth (Maximum allowed per IEC60601-1:

Patient Applied Part	Type B	Type BF	Type CF
Normal Condition	100µA	100µA	10µA
Single Fault	500µA	500µA	50µA

■ 3rd Edition by Classification:

Classification	Isolation	*Creepage/Clearance	Insulation
One MOOP	1500Vac	2.5/2.0 mm	Basic
Two MOOP	3000Vac	5/4.0 mm	Double/Reinforced
One MOPP	1500Vac	4/2.5 mm	Basic
Two MOPP	4000Vac	8/5.0 mm	Double/Reinforced

*The creepage/clearance are for a maximum working voltage of 250 Vrms/354 Vpk for an operating altitude of up to 2000 m (MOOP) and 3000 m (MOPP).

■ Other less common safety standards:

■ IEC61010-1

Definition: Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use

■ UL8750: Safety Standard for LED Lighting.

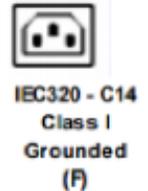
Scope: The standard covers LED equipment that is part of a luminaire or other lighting equipment operating in the visible light spectrum.

■ Class 2, UL1310

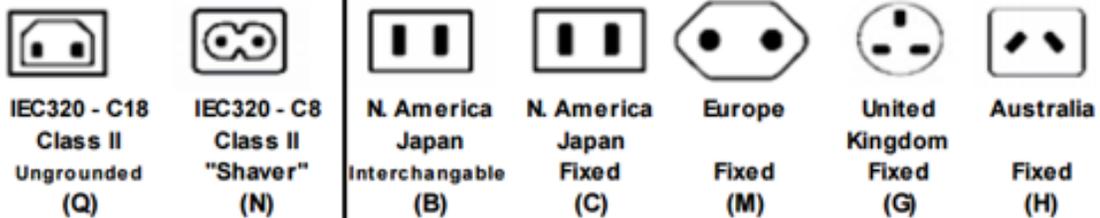
Definition: These requirements cover indoor and outdoor use for Class 2 power supplies, LED drivers, and battery chargers. The UL1310, Class 2 standard sets limits on the source with limited voltage and energy capacity.

Classes of equipment

- **Class I** – Class I equipment is protected against electric shock by (Earthed) additional protection to basic insulation through means of connecting exposed conductive parts to the protective Earth in the fixed wiring of the installation.



- **Class II** - Class II is also referred to as Double Insulated. Equipment protection against electric shock by additional protection to basic insulation through means of supplementary insulation are provided, there being no provision for the connection of exposed metalwork of the equipment to a protective conductor and no reliance upon precautions to be taken in the fixed wiring.



- **Class III** — Class III equipment is defined in some standards where protection against electrical shock relies on the voltage being less than 60Vdc or 42.4Vac_pk referred to as Safety Extra Low Voltage (SELV). Generally, these are battery power or powered from a SELV power source.

Sampling of Worldwide Safety Certifications

Region	Country	Safety Logo
North America	USA	
	Canada	
Latin America	Argentina	
	Brazil	
	Mexico	
Europe	Denmark, France, Germany, Italy, Netherlands, Poland, Spain, Sweden, Switzerland, UK	
	Russia	
	Ukraine	
Asia Pacific	Australia/NZ	
	China	
	Hong Kong	
	Japan	
	Korea	
	Singapore	
	Taiwan	

Definitions

- **Certified Body Scheme** - The CB Scheme is a vast international arrangement established by the International Electrotechnical Commission (IEC) for mutual acceptance of safety test reports among participating certification organizations in the field of electrical and electronic equipment.
- **MOOP** – Means of Operator Protection
- **MOPP** – Means of Patient Protection
- **Applied Part** – Part of the medical equipment designed to or likely to physically contact the patient.
- **LPS** – Limited Power Source
- **Safety Extra Low Voltage (SELV)** - circuits where voltage levels cannot exceed 42.4 V pk ac or 60 Vdc, under both normal and single fault conditions.
- **Insulation and Isolation:**
 - **Operational/Functional:** Insulation for correct operation of equipment
 - **Basic Insulation:** Insulation to provide basic protection against electric shock.
 - **Supplementary Insulation:** Independent insulation applied in addition to basic insulation to ensure protection against electric shock in the case of a failure of basic insulation.
 - **Double Insulation:** Insulation that includes both basic and supplementary insulation.
 - **Reinforced Insulation:** Provides a single insulation system that offers a degree of protection against electric shock equivalent to double insulation.
- **Leakage Currents:**
 - **Earth Leakage Current:** Is the current that flows through the ground conductor of the line cord back to ground.
 - **Enclosure Leakage Current:** Is the current that flows from any part of the enclosure through a person and back to ground is touched by a person.
 - **Patient Leakage Current:** applies to medical devices and is the current that flows through a person to ground having an applied part by applying an unintended voltage from an external source.
- **UL94 Enclosure Flame Rating:**
 - **HB:** Slow burning on a horizontal specimen; burning rate < 76 mm/min for thickness < 3 mm or burning stops before 100 mm
 - **V-2:** Burning stops within 30 seconds on a vertical specimen; drips of flaming particles are allowed.
 - **V-1:** Burning stops within 30 seconds on a vertical specimen; drips of particles allowed as long as they are not inflamed.
 - **V-0:** Burning stops within 10 seconds on a vertical specimen; drips of particles allowed as long as they are not inflamed.

■ Ground Symbols & Earth Ground:



SYMBOL	TITLE	SHORT NAME
	Earth (ground)	EGND
	Functional Earth (ground) – symbol also used for Functional Earth per IEC60601-1 Cl. 7.2.19 and IEC60950-1 Cl. 2.6.2.	FGND
	Noiseless (clean) earth (ground)	NEGND
 Correct Incorrect	Protective Earth (ground)	PEGND
	Frame or Chassis	CHGND
	Equipotentiality	EQGND

Example of an Earth Ground connection: Metal water pipe used as earth ground connected to AC utility panel.

- **ROHS** - ROHS is the acronym for Restriction of Hazardous Substances. RoHS, also known as Directive 2002/95/EC, originated in the European Union and restricts the use of specific hazardous materials found in electrical and electronic products.
- **REACH** - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) is a European Union Commission (EUC) Regulation on chemicals and their safe use (EC 1907/2006) entered into force on 01 June, 2007 and will be phased in until 2018.
- **Guide to International Input plug type** – Reference from Interpower:

<http://www.interpower.com/ic/designers/designing-for-export/guides-and-charts/Guide-WW-P&S-1-15.pdf>

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