Guangzhou Quankang Technology Co., Ltd.

Medical Power Supply Certification Guide

IEC 60601-1 · Class II · Global Approvals · EMC & Home Healthcare

For Medical Device Manufacturers & Design Engineers

Quankang power supply | https://quankang-cn.com/

Selecting a medically approved power supply starts with confirming its certifications, not just product specifications. This guide covers four core certification areas that Quankang comply with, helping your device compliance review start from a solid foundation.

CHAPTER 01

IEC 60601-1 Core Medical Safety Standard

IEC 60601-1 is the foundational safety standard for all medical electrical equipment. Any power supply used in a medical device must comply with this standard to enter regulated markets. Quankang medical PSUs meet both the Third and Fourth Editions.

3rd Edition vs 4th Edition

	3rd Edition (IEC 60601-1:2005)	4th Edition (IEC 60601-1:2020)
Status	Widely accepted globally	Increasingly required (EU, Canada)
Risk Mgmt	Basic risk assessment	Enhanced risk mgmt (ISO 14971)
Usability	Limited requirements	Mandatory usability engineering
Software	Basic software lifecycle	Full IEC 62304 integration
Quankang	Yes — all current models	Yes — all current models

Key Technical Requirements

2×MOPP
Two Means of Patient Protection — minimum isolation requirement for patient-connected devices. Quankang medical PSUs provide reinforced insulation between input and output.

BF Rated
Body Floating type applied parts allow direct patient contact. Open Frame and Enclosed series support BF-rated configurations for devices requiring physical patient connection.

Leakage Current
Earth and patient leakage currents must be controlled to safe limits. All Quankang medical PSUs are designed with leakage current ≤100μA under normal conditions.

Creepage/Clearance
Physical separation between conductors meets minimum distances defined by working voltage and pollution degree. Designs validated to 250V / Pollution Degree 2 as standard.

CHAPTER 02

Class II Insulation Double Insulation Design

Class II power supplies use reinforced or double insulation instead of a protective earth connection. This design is particularly suited for portable and handheld medical devices where a grounded enclosure is not practical for patient-contact applications.

Class I vs Class II — Key Differences

	Class I	Class II
Protective Earth	Required	Not required
Insulation	Basic insulation + earth	Double / reinforced insulation
Plug	3-pin	2-pin
Typical use	Fixed industrial / lab equipment	Portable & handheld medical devices
Patient safety	Depends on earth integrity	Independent of earth connection
Quankang products	Selected models	Desktop & Wall Mount series

Suitable Device Categories

The following are Quankang's primary application areas — all with verified UE model references:

Diagnostic & Monitoring	Blood glucose monitor, ECG machine, patient monitor, portable ultrasound, sleep apnea monitor
Respiratory Care	Ventilator, oxygen concentrator, nebulizer
Personal & Home Healthcare	Hair removal device, laser hair growth device, cosmetic laser device, wearable health monitor, sleep headband, hearing aid
Maternal Care	Breast pump, fetal monitor, formula maker
Sports Medicine & Rehabilitation	Electric prosthesis, low-frequency therapy device, patient monitor display
Dental & ENT Equipment	Dental light curing unit, intraoral scanner, dental floss machine, hearing aid charger
Infusion & Drug Delivery	Infusion pump, syringe pump, insulin pump
Medical Aesthetics	Laser hair removal, CO2 laser treatment, UV skin detector, tattoo machine, semiconductor laser therapy

CHAPTER 03

Global Market Certifications Medically Approved

Entering regulated medical device markets requires market-specific certifications beyond IEC 60601-1. Quankang products carry certifications for key global markets including North America, Europe, Japan, Korea, and Brazil.

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Certification	Region	Regulatory Body	Notes
CE (MDR)	European Union	Notified Body	Required for EU market; covers safety & EMC
UL / cUL	USA / Canada	UL (OSHA NRTL)	Aligns with IEC 60601-1 4th Edition
FCC	USA	FCC	EMC / radio emissions compliance
CB Scheme	60+ countries	IECEE CB Scheme	Single test report for multi-market approval
PSE	Japan	METI / JET	Mandatory for Japan market
KC	South Korea	KATS / KTC	Required for Korean market
BIS	India	Bureau of Indian Standards	Mandatory for India market

CB Scheme — The Efficient Path to Multi-Market Approval

A single CB Test Report from an accredited NCB can be used to obtain national certifications in over 60 member countries, significantly reducing duplicate testing costs and lead time. Quankang recommends CB Scheme testing as the baseline for any device program targeting more than two markets.

How to Choose the Right Certification

Step 1	Identify your primary target market(s) and confirm the mandatory certification requirement.
Step 2	Check whether your device classification (Class I/II, BF/CF type) affects the certification scope.
Step 3	Consider CB Scheme as a base test to streamline multi-market submissions.
Step 4	Contact Quankang to confirm which models carry the certifications needed, or discuss ODM options.

CHAPTER 04

EMC & Home Healthcare IEC 60601-1-2 / IEC 60601-1-11

Medical power supplies must also comply with electromagnetic compatibility (EMC) standards and, for devices used outside clinical settings, the additional requirements for home healthcare environments.

IEC 60601-1-2 — Electromagnetic Compatibility

IEC 60601-1-2 defines EMC requirements for medical electrical equipment — both emissions (interference the device generates) and immunity (how well the device withstands external in[illegible] ba[illegible]

Requirement	Standard	What It Covers
Radiated Emissions	CISPR 11	RF noise radiated by the power supply
Conducted Emissions	CISPR 11	Noise conducted back into the mains supply
ESD Immunity	IEC 61000-4-2	Electrostatic discharge tolerance
Radiated Immunity	IEC 61000-4-3	Immunity to RF fields (80 MHz–2.7 GHz)
EFT/Burst Immunity	IEC 61000-4-4	Fast transient burst on power lines
Surge Immunity	IEC 61000-4-5	Lightning / switching surges
Conducted Immunity	IEC 61000-4-6	Immunity to conducted RF disturbances
Voltage Dip Immunity	IEC 61000-4-11	Power supply interruption tolerance

Quankang Self-Built EMC Laboratory

Quankang operates an in-house EMC laboratory benchmarked against German TUV and Swiss SGS standards, covering both radiated and conducted emission compliance testing. This enables faster design iteration and pre-compliance verification before formal third-party testing, reducing certification lead time.

IEC 60601-1-11 — Home Healthcare Environments

IEC 60601-1-11 applies additional requirements for medical devices intended for home use — settings outside professional healthcare facilities where conditions are less controlled.

- Higher electromagnetic immunity — accounts for consumer electronics interference in residential environments
- Wider operating temperature range: 0°C to 40°C (vs. 10°C to 40°C for clinical)
- Lower altitude: validated for use up to 3,000m (vs. 2,000m standard)
- Enhanced ingress protection — tolerates higher humidity and occasional liquid exposure

Note: IEC 60601-1-11 compliance is required in addition to IEC 60601-1 — it does not replace the base standard. Quankang Medical USB series and External series products are validated to IEC 60601-1-11 where applicable.

Not sure which certification your device needs?

Contact Quankang's technical team for a certification consultation tailored to your device type and target market.

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