

Medical Equipment Regulated by DENAN (PSE Mark)

Medical equipment is generally regulated by Japan's Pharmaceutical Affairs Law (PAL). Certification processes for medical equipment under PAL vary depending on the potential risk of medical equipment. UL Japan is accredited by Japan's Ministry of Health, Labour and Welfare (MHLW) for most Class II equipment. Please contact UL Japan for the PAL services which they provide.

Several of medical equipment are also regulated by DENAN (PSE Mark). The following products need a PSE Mark and may be also regulated by the PAL.

- Bubble generating bathes
- **DC power supply units***
- Electric hair clippers
- Electric inhalators
- Electric massagers
- Finger pressure (Shiatsu) simulators
- High-frequency hair removers
- Household electric potential therapeutic apparatuses
- Household heating therapeutic apparatuses
- Household low frequency therapeutic apparatuses
- Household short wave therapeutic apparatuses
- Household therapeutic lighting apparatuses
- Household ultrasonic apparatuses
- Magnetic therapeutic apparatuses
- Motor-driven reclining bed
- Other household electric motor-operated or magnetically driven apparatuses for household therapeutic use
- Producers of medical materials

Note for DC power supply units*:

Detachable DC power supply units (AC/DC power adaptors) intended for medical use need a PSE Mark. Since MHLW does not consider the power supply unit itself as a medical device, medical device including a detachable power supply needs an additional approval for PAL as a system.

METI has not adopted IEC60601-1 for PSE Mark. To obtain PSE Certificate for medical-use power supplies, the following options are available;

Option 1: CB Test Certificate/ Report issued for IEC60950: 1999, including Japanese National Differences.

Option 2: CB Test Certificate/ Report issued for IEC60950-1. In this case, Japanese National Differences from IEC60950: 1999 shall be completed and attached to Miscellaneous Enclosure of CB Test Report.

Option 3. Testing in accordance with Shorei 1 (Japanese traditional standards). Tests shall be conducted at NBK, MEL or UL Japan office.