# **Electrical Products & Medical Devices**

# **Our Services**

## **Mandatory Approvals in Japan**

#### Electrical Safety (PSE mark)

JQA issues Certificates of Compliance as a METI-registered conformity assessment body.

Certification Scope: (as of Sep. 24, 2015)

- Electronic appliances
- AC electric appliances (excluding those listed in the Enforcing Rules of the Electrical Appliance and Material Safety Law, Article 19, Items 2 to 8)
- Single-phase small power transformers and discharge lamp ballasts
- Electric heating appliances
  - appliances

• Electric motor-operated

#### Consumer Product Safety (PSC mark)

JQA conducts testing and certification of portable lasers.

#### Medical Device Requirements (MHLW)

JQA issues Marketing Authorization for medical devices as an MHLW-registered certification body (RCB).

Certification Scope: (as of Sep. 24, 2015)

- Highly-controlled medical devices

   insulin pens
   heparin-coated arterial line blood filters for use in cardiopulmonary bypass circuits
   heparin-coated, single-use cardiopulmonary bypass defoamers
   enteral infusion pumps
   general-purpose infusion pumps
   syringe infusion pumps
   patient-controlled analgesia infusion pumps
   Reusable and single-use manual resuscitators
- Controlled medical devices
   Active Implantable Devices
   Anasthetic/respiratory devices
   Dental devices
   Medical electrical devices
   Clinical equipment
   Non-active implantable devices
   Ophthalmic devices
   Reusable devices
   Single-use devices
   Hearing aids
   Diagnostic radiological and imaging devices
   Homeuse massage and therapeutic devices (and related items)
- In vitro diagnostic medical devices
   In vitro diagnostic medical devices

### Radio Equipment (MIC)

As an MIC-registered certification body, JQA issues Certificates of Conformity to Technical Standards for radio equipment.

Certification Scope: (as of Sep. 24, 2015)

- Test station for dedicated short range communications system
- UWB radio systems (UWB radar)
- Low-power data communications systems in the 2.4GHz band
- Low-power data communications systems in the 5.2, 5.3GHz band
   Low-power data communications systems in the 5.6GHz band for outdoor use
- Millimeter wave image transmission and Millimeter wave data transmission
- Land mobile stations for 5GHz band wireless access system
- Digital cellular telephone (narrow-band TDMA)
- Digital cellular telephone (wide-band TDMA)
- Low-power wide-band data communications systems in the 2.4GHz band (for outdoor radio control model aircraft)
- Low-power data communications systems in the 2.4GHz band (for

outdoor radio control model aircraft)

- Citizen radio
- Specified low-power radio
- equipmentUWB radio systems
- 26GHz UWB systems

# **Other Certification Services**

#### S-JQA Mark Certification

The S-mark is a voluntary safety certification scheme in Japan. The S-mark is displayed on over 75% of electronics sold in Japan and is well-recognized by consumers.

#### CMJ Registration

CMJ Registration is a voluntary scheme to assess and register components and materials. Voluntary registration can reduce required testing of end-products for the PSE mark and improve marketability of components and materials.

#### ■IECEE CB Certification

JQA is an NCB in the IECEE CB Scheme administered by the IEC and IECEE.

Certification Scope: (as of Sep. 24, 2015)

- SAFE: Transformers and similar devices
- HOUS: Household products
- MED: Medical devices
- OFF: Office and IT equipment
- MISC: Other products
- E3: Energy efficiency
   MEAS: Measurement equipment
- EMC
- TRON: A/V & gaming devices

#### ■IECQ Certification

JQA can conduct IECQ certification of components and materials, as well as IECQ system certification of companies that test, design, manufacture, and distribute components and materials.

#### BSMI Certification (Taiwan)

JQA obtained BSMI accreditation through an MRA between Japan and Taiwan. JQA can conduct testing, factory inspections, and issue Certificates of Compliance (CoC). CoCs can be submitted to BSMI to quickly obtain RPC certification.

## **Global Market Access**

#### International Approvals

Utilizing an extensive network of regulatory and certification bodies, JQA can provide application services for approvals in over 50 countries.

#### Globally recognized test results

Through agreements with our partners overseas, JQA is able to offer local testing in Japan for a number of other countries' certification systems. Please contact us for information regarding a specific country.

- Cordless telephoneLow-power security systems
- PHS land mobile stations

# **Testing Services**

#### Safety

JQA conducts testing pursuant to domestic, international, and industry standards.

#### Products

- Medical equipment
- . A/V equipment
- Measuring equipment
- Embedded power supplies

Standards

- JIS standards and technical requirements in Japanese Laws •
- International standards (ISO, . IEC. etc...)
- . Industry standards

#### ■EMC

#### Products

• All electrical and electronic products (including medical)

#### Testing

- EMI
- Harmonic current emissions
- - Voltage fluctuations and flicker

Household electronics

Materials and components

Regional standards (EN, GB,

IT equipment

Li-ion batteries

Custom testing

etc...)

EMS

#### Schemes & Standards

- EMC for Japan's radio, safety, and medical device laws
- . EMI testing for VCCI (IT equipment)
- Testing for international standards such as IEC & CISPR
- FCC testing for the USA
- IC testing for Canada
- . KC-mark certification testing for Korea
- . BSMI certification testing for Taiwan
- EAC certification testing
- . E-mark testing and other EMC testing for devices to be used in automobiles
- EMC testing for classification societies .

#### Wireless & communications devices

- RF testing for domestic & international approvals
- SAR testing
- EMF testing

### Energy Efficiency

- Energy Star Program (USA)
  - Computers · Displays · Imaging Devices · TVs
  - California Energy Commission (USA) •TVs •DVD •Compact audio •External power supplies Small battery charger systems
- Testing for the International Energy Star Program
- Custom energy efficiency testing

### ■IP Code

Testing pursuant to the IP Code in JIS C 0920 (harmonized to IEC 60529) to rate a product's resistance to intrusion by water and dust.

- Waterproof (IPX1 - IPX8)
- Dustproof/dust resistance (IP1X - IP6X)

#### LED Lighting

Testing for LED lamps, LED luminaires, and LED power supplies.

- Electrical safety
- Performance

#### Lasers

Testing pursuant to JIS C 6802 (harmonized to IEC 60825 for laser radiation safety).

- Measurement of laser power and Class category according to risk level
- Compliance to JIS standards

#### Other testing

Additionally, JQA maintains equipment for the following tests. Please contact us for testing to a specific standard.

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Vibration

Sound power level

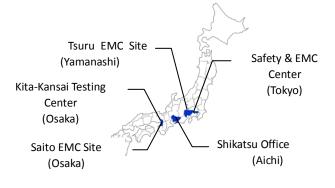
Shock

- Temperature and humidity
  - Thermal shock
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Please contact us to submit an application or for more information about domestic and international certification schemes and technical requirements.

# **Our locations**

### Visit us at any of our five locations in Japan.



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- Photobiological safety Total luminous flux

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- Suction power
- Inquiries

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