INTEGRA

Compliance Battery Regulations

The **M**inistry of **E**conomy, **T**rade and **I**ndustry (経済産業省, *Keizai-sangyō-shō*) or **METI**, is a ministry of the government of Japan. It was created by the 2001 central government reform when the **M**inistry of **I**nternational **T**rade and **I**ndustry (MITI) merged with agencies from other ministries related to economic activities. **METI** has jurisdiction over a broad policy area, containing Japan's industrial/trade policies, energy security and control of arms exports. Among these is the safety of electrical appliances and installations.
In Japan the Electrical Appliances and Materials Safety Act (Act No. 234 of November 16, 1961 and subsequent amendments, Japanese: 電気用品安全法 / *Denki Yohin Anzenhou*) also known as **DENAN** law regulates among many other items lithium ion batteries. This law also stipulates marking requirements with the **PSE** (for **P**roduct **S**afety of **E**lectrical appliances) sign.

On 1 February 2019, an amendment to the DENAN Act came into force (https://www.meti.go.jp/english/press/2018/0201_001.html), which also regulates lithium cells and batteries that are permanently installed in mobile devices, which were previously excluded.

This was followed by a partial revision of the 'On the Interpretation of the Ministerial Regulation on the Specification of Technical Requirements for Electrical Equipment and Materials'.
METI announced that Annex 12 of the 'About Interpretation of Ministerial Ordinance for Establishing Technical Requirements for Electrical Appliances and Materials' was revised on 31 January 2025. The effective date of this revision is 1 February 2025.
The revision from J61558-1(2019) to J61558-1(2025) was made without a grace period and J61558-1(2019) was deleted from Annex 12. The existing standards except J61558-1(2019) (see the current standard number in the table below) remain valid until 31 January 2028.

1 PSE marking

Lithium-ion cells and batteries are classified "Other Electrical Appliances and Materials (Category B)" under the DENAN Law in Japan. This means that these products require **self-certification** and **registration** by the manufacturer or importer in order to obtain the PSE mark.
Key points are:

- Self-certification and registration: Importers or manufacturers must register and have the batteries or cells tested to ensure they meet the technical requirements.
- PSE Mark: After successful certification and registration, the PSE mark can be applied to the product. For lithium-ion batteries and cells, this is typically the circular PSE mark.

These requirements apply to both manufacturers within Japan and importers. Once all regulations are met, the use of the PSE mark is permitted.

Lithium-ion batteries are listed under Article #341 in Category B of the DENAN Law. However, there are certain exceptions:

- Batteries for automobiles, motorized bicycles, medical equipment, and industrial equipment are excluded from this regulation.
- Batteries with less than 400 watt-hours per liter are also exempt.

These exceptions ensure that particularly high-power batteries, or those used in specific applications such as automobiles or medical devices, are not subject to the same requirements as standard lithium-ion batteries.

2 Regarding UN 38.3

This document summarizes lithium battery tests as required by IATA's updated 2019 Lithium Battery Guidance Document, which states: Effective 1 January 2020, manufacturers and subsequent distributors of cells or batteries and equipment powered by cells and batteries manufactured after 30 June 2003 must make available the test summary as specified in the UN Manual of Tests and Criteria, Revision and Amendment 1, Part III, sub-section 38.3, paragraph 38.3.5. Additionally, starting from 1 January 2025, there will be updates to regulations for sodium-ion batteries

3 INTEGRA's commitment

INTEGRA Biosciences manufactures products exclusively for laboratory use, ensuring they are handled only by trained professionals. Their lithium batteries undergo rigorous testing to meet international safety standards, including UN38.3 and IEC62133, on which the Japanese standard JIS C 62133 is based.
These tests ensure the batteries are safe for use and transport, addressing risks such as overheating, short circuits, and fire hazards. This compliance guarantees the reliability and safety of INTEGRA products in laboratory environments.

PIPETBOY ACU2 and VACUSIP (Art No 159603 Li-ion Polymer Battery 3.7V 550mAh 350 Wh/l)

The cell used in this battery is a KPL652339 lithium polymer cell with 6.5mm thickness, 12mm width and 39mm length. It has a nominal voltage of 3.7V and a capacity of 550 mAh, resulting in an energy density of 350 Wh/l. Battery blocks **INTEGRA Art No 159603** contains two cells connected in series. The battery block has physical dimensions compatible with IEC 6F22 / 6LR61 or ANSI 1604A. These formats are also known as "9V block" worldwide, PP3 in the U.S. or 006P in Japan. The battery **INTEGRA Art No 159603** include a protective circuit limiting maximum and minimum cell voltage as well as protecting the cells against short circuit. **INTEGRA Art No 159603** batteries are used in **INTEGRA PIPETBOY Acu 2** and **INTEGRA VACUSIP** and can be replaced by the user in case of **INTEGRA PIPETBOY Acu 2** without the use of a tool. The battery/cell is comply with UN38.3.

VIAFLO and VOYAGER Pipettes (Art. No. 161700 Li-ion Cylindrical Battery 3.7V 1200mAh 390 Wh/l)

The cell **INTEGRA Art No 161700** is an ICR14650 lithium-ion cell with a diameter of 14mm and a length of 65mm including a wired connector. It has a nominal voltage of 3.7V and a capacity of 1050 mAh, resulting in an energy density of 390 Wh/l. These cells do not feature a protective circuit, but they can only be connected with a special connector preventing their use in incompatible equipment from other manufacturers. Protective circuits are used in compatible **INTEGRA Biosciences** products to limit maximum and minimum cell voltage as well as to protect the cell against short circuit. **INTEGRA Art No 161700** cells are used in **INTEGRA VIAFLO** and **INTEGRA VOYAGER** pipettes and can be replaced with the help of a tool. The battery or cell is complies with UN38.3.

SWITCH hybrid pipette (Art.No. 120700 Li-ion Battery 3.7 V 605mAh 2.24 Wh)

The **INTEGRA** SWITCH uses a Li-ion POLYMER rechargeable battery with the following specifications:

- Approx. Weight: 11.3g
- Cell Dimensions: Height around 75mm, Width 25mm
- Energy Density: 399 Wh/l

The battery/cells comply with international safety standards:

- IEC 62133-2:2017 (Japanese safety standard for lithium-ion cells)
- UN 38.3 (Regulations for the transport of lithium-ion batteries)

This ensures that the battery meets recognized safety and performance standards for reliable use in the **INTEGRA** SWITCH.

Regulatory Statement

Because of the exclusive use by professionals in research and microbiology labs **INTEGRA Biosciences** considers its lithium batteries generally to be covered by the "industrial equipment" exemption of the **DENAN** regulations.
All three **INTEGRA Biosciences** Lithium ion batteries **Art No 159603, 161700** and **120700** are also exempt from **DENAN** regulations because their energy density is less than 400 Wh/l.

PIPETBOY GENIUS (Art. No. 130606 3.7V 1300mAh 4.44Wh Li-ion Cylindrical Battery)

The **INTEGRA PIPETBOY GENIUS** uses a Li-ion cylindrical rechargeable battery with the following specifications:

- Weight: Approx. 28g
- Cell Dimensions: Height 67mm, Diameter 16mm

The battery/cells comply with international safety standards:

- JIS C 62133-2:2020 (Japanese safety standard for lithium-ion cells)
- UN 38.3 (Regulations for the transport of lithium-ion batteries)
- UL 1642 (Underwriters Laboratories safety standard for lithium batteries)
- GB 31241 (Chinese safety standard for lithium batteries in portable devices)

Additionally, the device is certified with the **PSE mark**, confirming compliance with Japanese safety regulations for electrical products. The battery can be replaced without the help of a tool.

4 Signature

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