

April 14, 2015

To:

Product Safety Division
Commerce Distribution and Industrial Safety Policy Group
Ministry of Economy, Trade and Industry

From:

The Japan Federation of Medical Devices Associations
(JFMDA)
American Medical Devices and Diagnostics
Manufacturers' Association (AMDD)
Medical Equipment Committee, European Business
Council (EBC)

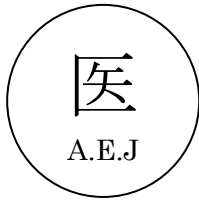
**Voluntary Actions to a Direct Current Power Supply Unit (AC Adaptor)
to be Taken by three Medical Device Industry Bodies**

With the announcement (dated January 22, 2015) that direct current power supply unit (AC adaptor) designed for integral use with specially controlled medical devices and controlled medical devices designated in the Pharmaceutical and Medical Device Act will be excluded out of the scope of the Electrical Appliances and Material Safety Act, it is recommended that such AC adaptors used for other than medical institutions be marked with a symbol that instantly tells that they are integral parts of medical device. That mark will be attached in lieu of the current PSE mark.

The three medical device organizations will take actions to any AC adaptor intended for use with devices in other than medical institutions in the following manner.

1. Current practice will be followed for devices whose conformity with PSE has been confirmed.
2. AC adaptors whose electrical safety has been confirmed and approved/certified as medical devices pursuant to an international standard recognized by Electrical Appliances and Material Safety Act in lieu of PSE compatibility, and which are intended for use by other than medical institutions shall have a voluntary mark on their body, Their explanation documents shall incorporate meaning of the voluntary mark. At the same time, AC adaptors whose conformity with PSE has also been confirmed may have a voluntary mark in the vicinity of the PSE mark.

- Voluntary Mark (TBD)



There will be no requirements or restrictions in color and size of the above mark. The design will be made in an original plate of photo printer. The A.E.J in the mark stands for AMDD, EBC and JFMDA.

End

Note:

[Inclusion of the mark in Product Handling Manuals]

All manuals of the applicable AC adaptors shall include the following sentence or others equivalent to it: “The 医 mark on this product refers to that this product is in conformity with an electrical safety test as medical device, which is equivalent to PSE (Electrical Appliances and Material Safety Act).”

[Display of this Document on the WEB sites of the Respective Organization]

The proposal contained in this document will be uploaded to the website of the respective organization under the title of ‘Our Voluntary Actions to Respond to the Changes in the Scope of PSE Medical Device.’