Provisional Translation (as of November 2023)[*]

PSEHB/MDED Notification No.0930-1
PSEHB/CND Notification No.0930-1
September 30, 2022

To: Directors of Prefectural Health Departments (Bureaus)

Director of the Medical Device Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Director of the Compliance and Narcotics Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Handling of revision of Japanese Industrial Standards concerning requirements for usability engineering of medical devices

With regard to the application of “Standards for Medical Devices Specified by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 41, Paragraph 3 of the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices” (Ministerial Notification No. 122 of 2005; hereinafter referred to as “Essential Principles”) pertaining to usability engineering of medical devices, "Concerning the Handling under the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices in Accordance with the Establishment of the Japanese Industrial Standards for the Application of Usability Engineering to Medical Devices" (PSEHB/MDED Notification No. 1001-1 and PSEHB/CND Notification No. 1001-5, Joint Notification of Director of the Medical Device Evaluation Division and Director of the Compliance and Narcotics Division, dated October 1, 2019; hereinafter referred to as “2019 Notification”) indicates the handling of the Japanese Industrial Standard “JIS T 62366-1:2019, Medical devices－Part 1: Application of usability engineering to medical devices”.

[*] This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

JIS T 14971, Medical devices－application of risk management to medical devices, which is the normative reference standard of JIS T 62366-1 has been revised, which also clarifies the application to usability and other relevant area. Following the revision of JIS T 14971, JIS T 62366-1:2019 was also revised to JIS T 62366-1:2022 (hereinafter referred to as “revised JIS”). In response to this revision, the handling in the “Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices" (Law No. 145 of 1960; hereinafter referred to as the “Act”) has been stipulated as follows. Please inform the relevant organizations under your supervision. This notification shall be effective as of October 1, 2012, and the “2019 notification” will be abolished in accordance with the application of this notification.

***

1. Confirmation of compliance with Essential Principles

(1) The market authorization holders of the medical device, persons with special approval for foreign-manufactured medical device or foreign manufacturers of designated specially-controlled medical devices (hereinafter referred to as “MAH”) shall establish a system to verify compliance with the usability related requirements specified in Article 9 and Article 16, etc. of the Essential Principles for the medical devices to be marketed after March 31, 2024 (hereinafter referred to as "end of the transition period") with conformity to the revised JIS.

Necessary measures, such as revision of procedures, shall be taken to ensure conformity to the revised JIS by the end of the transition period.

(2) Other than the revised JIS, the compliance with Article 9 and Article 16 etc. of the Essential Principles may be confirmed by conformity to the appropriate internationally used standards, etc. When applying for new approval or certification (including applications for partial changes in approval and applications for partial changes in certification; hereinafter referred to as “application for approval”), explain the appropriateness of using these alternative standards, etc.

(3) The MAH who applies for approval or certification of a specially-controlled medical device or controlled medical device on or after the day following the end of the transition period shall confirm the conformity of the medical device according to the system established in (1) above. The conformance to the revised JIS shall be explained in the attached data of the application for approval.

(4) When submitting a marketing notice on or after the day following the end of the transition period, conformity with the system established in (1) above shall also be confirmed.

2. The MAH shall conduct activities based on the revised JIS for the product realization specified in Article 26 and design and development specified in Article 30 to 36 of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-Vitro Diagnostics (MHLW† Ministerial Ordinance No. 169 of 2004) and shall appropriately record and store the confirmation of compliance.

   In addition, appropriate explanations must be provided by presenting data at the request of the person authorized to investigate pursuant to the provisions of Article 23-2-5, Paragraph 7 or Article 23-2-23, Paragraph 4 of the Act.

† The term “MHLW” refers to the “Ministry of Health, Labour and Welfare.”