

November 25, 2014

To: Directors of Health Departments (Bureaus) Prefectural Governments

Director of the Medical Device and Regenerative Medicine Product Evaluation Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare
(official seal omitted)

Handling of Application for Marketing Certification of Medical Device Software

In the “Act on Securing the Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics” (Act No. 145 of 1960; hereinafter, the “PMD Act”) amended according to the “Act for Partial Amendment of the Pharmaceutical Affairs Law” (Law No. 84 of 2013; hereinafter, the “Amending Act”) promulgated on November 27, 2013, “Software and storage media with the software recorded“ are additionally defined as medical devices. Their handling is stipulated in “Handling of Medical Device Software” (Joint PFSB/MDRMPE Notification No. 1121-33, PFSB/SD Notification No. 1121-1, and PFSB/CND Notification No. 1121-29, by the Director in charge of Medical Device and Regenerative Medicine Product Evaluation, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare (MHLW), the Director of the Safety Division, Pharmaceutical and Food Safety Bureau, MHLW, and the Director of the Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, MHLW, dated November 21, 2014; hereinafter, the “Software Fundamental Notification”).

Recently, the “Partial Amendment of Specially Controlled Medical Devices, Controlled Medical Devices and General Medical Devices Specified by the Minister of Health, Labour and Welfare according to the Provisions of Article 2, Paragraphs 5 to 7 of the Pharmaceutical Affairs Law” (Ministerial Notification No. 446 of 2014, by the Ministry of Health, Labour and Welfare) and “Partial Amendment of Medical Devices with Specific Standards Designated by the Minister of Health, Labour and Welfare according to the Provisions of Article 23-2-23, Paragraph 1 of the Act on Securing the Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics” (Ministerial Notification No. 445 of 2014, by the Ministry of Health, Labour and Welfare; hereinafter, the “Amendment Ministerial Notification”) have been promulgated. Under the “Medical Devices with Specific Standards Designated by the Minister of Health, Labour and Welfare pursuant to the Provisions of Article 23-2-23, Paragraph 1 of the Act on

* 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.

Securing the Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics” (Ministerial Notification No. 122 of 2005, by the Ministry of Health, Labour and Welfare) amended pursuant to the Amendment Ministerial Notification, specific standards have been established for software (hereinafter, “to-be-certified medical device software”). The details of the handling of marketing certification applications for to-be-certified medical device software are described in the following paragraphs. We request your cooperation in circulating and ensuring complete understanding of the information contained in this Notification by marketing authorization holders (MAHs), etc. under your supervision.

Please note that copies of this Ministerial Notification will be sent to the Chief Executive of the Pharmaceuticals and Medical Devices Agency (PMDA), the Chairperson of the Japan Federation of Medical Devices Associations, the Chairperson of the Medical Devices and Diagnostics Subcommittee of the American Medical Devices and Diagnostics Manufacturers’ Association in Japan, the Chairperson of the Medical Devices and Diagnostics Committee of the European Business Council in Japan, and the chief executive of each third-party certification body.

1 Application for marketing certification

For applications for marketing certification for to-be-certified medical device software or storage media with recorded medical device software, etc.” (hereinafter, “to-be-certified medical device software, etc.”), see the Ministerial Notifications entitled, “Application for Medical Device Marketing Certification” (PFSB Notification No. 1120-8, by the Director-General of the Pharmaceutical and Food Safety Bureau, MHLW, dated November 20, 2014) and “Points to Consider for Application for Medical Device Marketing Certification” (PFSB/MDRMPE Notification No. 1120-4, by the Director of the Medical Device and Regenerative Medicine Product Evaluation Division, Pharmaceutical and Food Safety Bureau, MHLW, dated November 20, 2014). In addition, regarding items to be inputted in each field of the marketing certification application form, refer to “Note 7 (1)-(9)” of the “Software Fundamental Notification.”

For to-be-certified medical device software, etc., substantial equivalency with medical devices using any approved or certified or medical device software, etc. (hereinafter, “Existing Products”) should be explained.

In addition, conformity to the specification requirements defined by the Japanese Industrial Standards (JIS) or the International Electrotechnical Committee (IEC), which are included in the certification standards, may not have to be presented if they are not applicable to medical device software, etc.

2 Handling of accessory functions

Regarding accessory functions presented in the “List of Accessory Functions in Designated Controlled Medical Devices (Part 1)” (PFSB/ELD/OMDE Notification No. 0608001, by the Director of Office of Medical Devices Evaluation, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW, dated June 8, 2005), etc., only function accessorially used by the to-be-certified medical device software, etc. are acceptable as with existing products. In application forms for marketing certifications for to-be-certified medical device software, etc. including accessory functions, the relevant product functions shall accordingly fall within the descriptions included in the respective certification form(s) of the existing product(s) from the perspective of comparability with such existing product(s). In addition, note that the intended use or indication must be appropriately described based on the definition of the generic name of the relevant medical device software, etc. such that the description(s) fall within the conformity certification standards and performance characteristics and intended use(s) yet to undergo standards conformity certification review with respect to the existing product(s) should not be described.

Whether accessory functions are to be classified as medical devices shall be determined on a case-by-case basis.

3 Handling of Standards for Essential Requirements

For handling of the “Standards for Medical Devices Specified by the Minister of Health, Labour and Welfare according to the Provisions of Article 41, Paragraph 3 of the Act on Securing the Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics” (Ministerial Notification No. 122 of 2005, by the Ministry of Health, Labour and Welfare; hereinafter, “Standards for Essential Requirements”), refer to the Ministerial Notification entitled, “Handling of the Standards for Medical Devices and *In Vitro* Diagnostics specified by the Minister of Health, Labour and Welfare according to the Provisions of Article 41, Paragraph 3 of the Act on Securing the Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics” (PFSB/MDRMPE Notification No. 1105-5, by the Director of the Medical Device and Regenerative Medicine Product Evaluation Division, Pharmaceutical and Food Safety Bureau, MHLW, dated November 5, 2014; hereinafter, the “Ministerial Notification concerning Standards for Essential Requirements”).

The checklist for conformity to the Standards for Essential Requirements (hereinafter referred to as “conformity checklist”) shall be based on the conformity checklist for medical devices using software provided in “Conformity Checklist of Designated Controlled Medical Devices” (PFSB/ELD/OMDE Notification No. 0331012, by the Director of the Office of Medical Device Evaluation, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW, dated March 31, 2005) and Appendix 1 of the Ministerial

Notification concerning Standards for Essential Requirements. The conformity status of to-be-certified medical device software, etc. with the Standards for Essential Requirements shall be confirmed using the aforementioned Conformity Checklist.

4. Scope of certified certification body activities

Activities related to standard conformity certification reviews are categorized in Appendix 1 of the Ministerial Notification entitled, “Handling of application for registration of third-party certification bodies under Article 23-2, Paragraph 1 of the Enforcement of the Act for Partial Amendment of the Pharmaceutical Affairs Law” (PFSB/MDRMPE Notification No. 1021-1, by the Director of the Medical Device and Regenerative Medicine Product Evaluation Division, Pharmaceutical and Food Safety Bureau, MHLW, dated October 21, 2014). The categories of activities related to standard conformity certification reviews of to-be-certified medical device software, etc. shall be those of medical devices using software with functions comparable to those of the medical device software in question.

5. Handling of transitional measures

Parties actually engaged in the marketing/distribution of to-be-certified medical device software, etc. at the time of enforcement of the Amending Act must submit an application for marketing certification for each product in accordance with the provisions of the PMD Act within three (3) months of the Effective Date. In addition, such parties may continue to market/distribute the products in question without marketing certification until the status of certification is determined. Note that the handling of transitional measures for other marketing business licenses, etc. are stipulated in Article 23 of the Supplementary Provisions to the Amending Act.