

To (described in Appendix)

Yasuhiro Fujiwara,
Chief Executive of Pharmaceuticals and Medical Devices Agency
(Official seal omitted)

Disclosure of Information Related to the Application for Confirmation of the Change Plan for
Medical Devices

Thank you for your continued understanding and cooperation in the operations such as the review of the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA").

Information on approved medical devices has been provided on the PMDA website as a list of approved medical devices.

From the viewpoint of promoting practical use of medical devices, we have decided to prepare a list of products for which confirmation of the application for confirmation of the change plan for medical devices has been completed and products for which marketing was approved as software as a medical device as follows and to provide information on the PMDA's website.

We therefore ask that you inform the members of your association so that all companies can cooperate in the disclosure of information related to the application for confirmation of the change plan for medical devices.

Notice

1. List of products for which confirmation of the application for confirmation of the change plan has been completed
 - (1) Scope of preparation

Medical devices for which confirmation of the application for confirmation of the change plan has been completed

- (2) Contents of information provided

The following information on the target medical device is listed and provided on the PMDA website.

- Date of completion of confirmation

* 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

- Confirmation No.
- Brand name
- Term name
- Name of marketing authorization holder

(3) Timing of provision

The contents shown in (2) of 1 will be organized every 6 months and promptly disclosed.

2. List of products approved for marketing as software as a medical device

(1) Scope of preparation

Medical devices whose main term name includes a term name as software as a medical device

(2) Contents of information provided

The following information on the target medical device is listed and provided on the PMDA website.

- Brand name
- Term name
- Approval No.
- Date of marketing approval
- Name of marketing authorization holder
- Application category
- Summary of the application (only for new medical devices and improved medical devices (with clinical data))
- Applicability to the following cases
 - Medical devices developed using AI
 - Medical devices utilizing Notice 2-(2) of "Handling performance evaluation tests of diagnostic medical devices using existing medical image data without additional invasion/intervention" (PSEHB/MDED Notification No. 0929-1 issued by the Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated September 29, 2021. Partially amended on March 17, 2025.)
 - Medical devices for which the first-step approval was obtained by utilizing the "Handling of the Two-step Approval Based on the Characteristics of Software as a Medical Device" (PSB/MDED Notification No. 1116-2 issued by the Director of the Medical Device Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare, dated November 16, 2023.)
- Link to the information provision website for medical devices for which information provision is required in Notice 2.(4) of "Partial Revision of the "Points to Consider for Approval Applications for Home Medical Devices to Detect Signs of Diseases and to Encourage Medical Consultation"" (PSEHB/MDED Notification No. 1213-4 and PSEHB/PSD Notification No. 1213-3 jointly issued by the Director of Medical Device Evaluation Division and the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated December 13, 2022. Partially amended on June 21, 2024.)

(3) Timing of provision

The contents shown in (2) of 2 will be organized every 3 months and promptly disclosed.

(Appendix)

President, the Japan Federation of Medical Devices Associations

Chairperson, American Medical Devices and Diagnostics Manufacturers' Association

Chairman, the EBC Medical Equipment and IVD Committee

Chairman, the Japan Digital Health Alliance

President, Japan Medical Venture Association

Chairman, Council for AI Medical Devices

President, Japan Pharmaceutical Manufacturers Association