Regulations on Unique Device Identification Management, Etc.

[Enforcement Date on Jul. 1, 2019] [Ministry of Food and Drug Safety Notice No. 2019-46, Established on Jun. 12, 2019]

Ministry of Food and Drug Safety (Medical Device Management Division), 043-719-3811

Article 1 (Purpose) The purpose of this Notice is to establish the necessary details on the information that medical device manufacturers and importers are required to register in the unique device identification (UDI) system (hereinafter referred to as "information, etc. on medical devices") pursuant to Article 31-3 of the Medical Devices Act and Article 54-2 (4) and Annex 7-2 of the Enforcement Rule of the same Act, along with the subject, scope of the information, registration method and procedures, etc.

Article 2 (Subject and Scope of Information, Etc. on Medical Devices) (1) The information that medical device manufacturers and importers are required to register in the UDI System shall be as follows:

1. Information on the unique device identifier (UDI), which falls under the following items:
   (a) Device identifier (UDI-DI) in the UDI;
   (b) Barcode labeling system (choose between GS1, HIBCC, and ICCBBA);
2. Information on a medical device product that falls under the following:
   (a) Total quantity in packaging;
   (b) For standalone software, information on its version;
   (c) Management format of the medical device (choose between lot number, serial number, date of manufacture, and expiry date);
   (d) Whether it is a sterile medical device;
   (e) For medical devices that require sterilization prior to use, whether the medical device needs to be sterilized;
   (f) `For the medical device that requires sterilization prior to use under item (e), the method of sterilization (choose between autoclaving, dry heat sterilization, ethylene oxide gas sterilization, medical formaldehyde gas sterilization, medical cold plasma sterilization, cold liquid sterilization, microwave sterilization, chlorine dioxide gas sterilization, and other sterilization method);
   (g) Whether the medical device is a health care benefit item under Article 41 of the National Health Insurance Act;
   (h) Where the medical device falls under the materials for medical treatment as a health care benefit item under item (g) (meaning the materials for medical treatment publicly notified pursuant to the main text of Article 8 (2) of the Rules on the Standards for Medical Care Benefits), the medical care benefit code (where the code is not provided, the reason shall be stated, and when the medical treatment benefit code is issued later, it shall be included);
   (i) Whether there are any fatal warnings or contraindications that fall under the following:

1) Whether LATEX is contained;
2) For a fluid set, whether phthalates, such as diethylhexyl phthalate (di-(2-ethylhexyl)-phthalate, DEHP) is contained;
3) Whether the medical device in use or implanted in a patient is safe when exposed to magnetic resonance imaging (MRI);

   (j) Whether it is an implantable medical device;
   (k) Whether it is a single-use medical device;

(l) Item name;
(m) Classification number (class);
(n) Product (product category) license, certificate, or notification number;
(o) Date of license, certification, or notification;
(p) Name (product name and model name). The product name applies only to products with a product number;
(q) Whether it is subject to tracking;
(r) For medical devices packaged in a set, the item name and class of each medical device;
(s) For composite medical devices, the item name and class of each medical device;

3. Information on the medical device manufacturer or importer (including foreign manufacturers) that falls under the following:
(a) Telephone number and e-mail address of the person responsible for UDI management;
(b) Trade name or name of the manufacturer or importer;
(c) Manufacturing or import business address;
(d) Manufacturer's or importer's address;
(e) For contracted manufacturing, the trade name or name, and the address of the manufacturer;
(f) For imported medical devices, the trade name or name, and the address of the foreign manufacturer.

(2) Medical device manufacturers and importers may register the following information in the UDI System, if necessary:
1. Storage condition;
2. Distribution and handling conditions;
3. URL address including electronic instructions for use (e-IFU), for further description of the product;
4. package DI;
5. Information on the consumer desk of the manufacturer or importer.

(3) Notwithstanding paragraph (1), information that falls under any of the following and is linked through the license information system of the Ministry of Food and Drug Safety may be exempt from registration:
1. Information under item (j) through (s) of paragraph (1) 2;
2. Information under item (b) through (f) of paragraph (1) 3.

Article 3 (Method for Registration of Information, Etc. on Medical Devices) When a medical device manufacturer or importer releases a medical device that has been licensed, certified, or notified, they shall register the information on medical devices pursuant to Article 54-2 of the Enforcement Rule of the Medical Devices Act and Article 2 of this Notice in the UDI System via electronic means such as the Internet.

Article 4 (Registration of Changes in Information, Etc. on Medical Devices) Medical device manufacturers and importers shall register changes in the UDI System within 10 days after the date of change in the information under item (b) through (i) of Article 2 (1) 2 or under Article 2 (1) 3 (a).

Article 5 (Confidentiality of Information) A person who learns about information on the manufacturer, etc. or product information that falls under a company secret in the course of his/her work shall not disclose the information to others or use it for purposes other than business purposes.

Article 6 (Re-review of Regulations) The validity of this Regulations shall be reviewed every three years from January 1, 2019 (by December 31 of every third year) pursuant to Article 8 of the Framework Act on Administrative Regulations and Rules on the Issuance and Management of Directives and Established Rules, and appropriate measures, such as

improvement measures, shall be taken.

ADDENDA <Notice No. 2019-46, Jun. 12, 2019>

This Notice shall enter into force on the dates as follows:

1. For Class 4 medical devices: July 01, 2019
2. For Class 3 medical devices: July 01, 2020
3. For Class 2 medical devices: July 01, 2021
4. For Class 1 medical devices: July 01, 2022