Instructions on Labeling and Management of Unique Device Identifiers

[Enforcement Date on May 1, 2020] [Ministry of Food and Drug Safety Notice No. 2020-29, Amendment by Other Act on May 1, 2020]

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

Article 1 (Purpose) The purpose of this Notice is to lay down the details in labeling and management of unique device identifiers (UDIs) that shall be specified on the container or outer package of medical devices manufactured in or imported to Korea under subparagraph 8 of Article 20 of the Medical Devices Act (hereinafter referred to as the "Act") and Articles 4 and 13 of the Act on In Vitro Diagnostic Medical Devices.

Article 2 (Definitions) The definitions of terms used in this Notice are as follows:

1. The term "unique device identifier (UDI)" means a combination of numbers or letters that are marked on containers, outer packages, etc. according to a standardized system to identify and systematically and efficiently manage medical devices. A UDI consists of a device identifier (UDI-DI) and a production identifier (UDI-PI);
2. The term "device identifier (UDI-DI)" means a combination of numbers or letters uniquely generated for each product as part of a UDI. It refers to the code that should be entered into the UDI system under Article 31-3 (2) of the Medical Devices Act;
3. The term "production identifier (UDI-PI)" means a combination of numbers or letters generated for each medical device production as part of a UDI. It should include information corresponding to any of the following items on the container or outer package:
   (a) Lot number (lot number, batch number, or serial number of the product);
   (b) Date of manufacture (expiry date, if any);
   (c) Version information of the product (for stand-alone medical device software only);
4. The term "medical device barcode" is a means for automatically entering the UDI into a computer. It is a symbol (mark) printed in a manner that can be read by a machine such as a scanner that falls under any of the following:
   (a) A combination of white and black parallel bars of various widths;
   (b) A matrix-based combination consisting of a set of square modules in a certain arrangement;
5. The term "radio frequency identification tag (RFID tag)" refers to a means of indicating a UDI using "radio frequency identification technology" and generally consists of a chip that stores the serial number of the PI in the UDI and an antenna that transmits the stored information.

Article 3 (Scope) This Notice applies to medical devices distributed or sold in Korea and does not apply to medical devices for export.

Article 4 (Generation of UDI) (1) A medical device manufacturer or importer shall generate a UDI using the Global Standard #1 (GS1) international standard system in accordance with Annex 1 for medical devices licensed, certified, or notified under Article 6 (2) or Article 15 (2) of the Act by the minimum designation unit (by model name; provided that, if there are multiple product names for one model, by product name) and by packaging unit.

(2) The manufacturer or importer under paragraph (1) shall re-generate the DI of the UDI for the medical device if any of the following changes occur:

1. In manufacturing, only the item or item category, excluding a business license, is transferred;
2. The minimum designation unit (model name or product name) is changed;
3. The packaging unit is changed;
4. Information on single-use or product sterilization is changed.

Article 5 (Labeling of UDI) (1) A medical device manufacturer or importer shall display or affix the UDI generated pursuant to Article 4 using any of the methods listed below, including the form of human-readable numbers or letters (hereinafter referred to as "readable characters"), on the container or outer package of the medical device manufactured or imported. In such case, it may be marked or affixed to the minimum packaging unit or the container, the outer package or the packaging of the packaging unit distributed to the final consumer.

1. Medical device barcode
2. A medical device RFID tag. In such case, the medical device barcode under subparagraph 1 shall be affixed, and a picture, shape, etc. indicating that a RFID tag is affixed shall be included.

(2) Where the UDI under paragraph (1) is affixed for medical devices falling under any of the following, permanent labeling shall be affixed on the outer package of the medical device:

1. A medical device that can be reused in a medical institution and is separately designated and publicly announced by the Minister of Food and Drug Safety;
2. A medical device that requires sterilization or other treatment before use, and is separately designated and publicly announced by the Minister of Food and Drug Safety.

(3) Notwithstanding paragraph (1), if the medical device software is supplied in an intangible form using an information and communications network rather than a computerized medium (e.g., diskettes or CDs), the UDI may be provided in a way that the user can verify after installing the product.

(4) In any of the following cases, the readable characters under paragraph (1) may be omitted:

1. Where a data matrix under item (c) of Annex 2;
2. Where the size of the barcode under Annex 3 is the same or smaller than the size of the container or outer package.

Article 6 (Instructions on Medical Device Barcode Labeling) (1) When displaying a medical device barcode on a medical device in accordance with Article 5 (1) 1, a European Article Number (EAN)-13 barcode, GS1-128 barcode, or GS1 Datamatrix barcode from the GS1 system shall be used.

(2) Instructions on Medical Device Barcode Labeling are as shown in Annex 2.

(3) The print size, color, and position of barcode on medical device that shall be in compliance in terms of medical device barcode labeling are as shown in Annex 3.

Article 7 (Instructions on Attaching RFID Tags on Medical Devices) (1) When attaching a RFID tag on a medical device under Article 5 (1) 2, Serialized Global Trade Item Number (SGTIN)-96 or Serialized Global Trade Item Number (SGTIN)-198 of a GS1 system shall be used.

(2) Instructions on generating RFID tags for medical devices are as shown in Annex 4.

(3) Selection criteria, attachment method, etc. for RFID tags for medical devices are as shown in Annex 5.

Article 8 (Special Cases concerning UDI) Notwithstanding Article 4 (1), Articles 6, and 7, a medical device manufacturer or importer may generate and label a UDI by utilizing an international standard system that falls under any of the following:

1. Health Industry Business Communications Council (HIBCC);
2. International Council for Commonality in Blood Banking Automation (ICCBBA).

Article 9 (Specific Matters) The head of the UDI Center under Article 31-4 (1) of the Act may set forth specific provisions separately if necessary to facilitate management and operation of UDI.

Article 10 (Re-review Period) The Minister of Food and Drug Safety shall review the validity of this Regulations every three years from January 1, 2019 (by December 31 of every third year) pursuant to the Rules on the Issuance and Management of Directives and Established Rules and take measures, such as improvement measures.

ADDENDA <Notice No. 2020-29, May 1, 2020>

This Notice shall enter into force on the date of its promulgation.

Annexes / Forms

[Annex 1] Instructions on Generating Unique Device Identifiers (concerning Article 4 (1))

[Annex 2] Instructions on Labeling of Medical Device Barcode (concerning Article 6 (2))

[Annex 3] Print Size, Color, and Position of Barcode on Medical Device (concerning Article 6 (3))

[Annex 4] Instructions on Generating RFID Tags for Medical Devices (concerning Article 7 (2))

[Annex 5] Selection Criteria, Attachment Method, Etc. for RFID Tags for Medical Devices (concerning Article 7 (3))