

Guidelines for Placing Standard Codes (Barcode Marking) on Medical Devices

Guidelines for placing standard codes (barcode marking) on medical devices have been established as below to promote efficient and sophisticated distribution systems, efficient medical administration, and securing traceability as well as prevention of medical accidents by refining distribution management from licensed marketing approval holders and manufacturers to medical institutions.

As these guidelines are standards to be promoted cooperatively by the medical devices industry and the administration, barcode marking should be promoted to this effect

1. Marking Subjects and Data to be Placed

1) Medical Devices, etc

Marking subjects are medical devices and in vitro diagnostics (*1). Depending on the type of product, the product code, expiration date (*2) and lot number or serial number should be placed as shown in the following table. (*3)

Marking on individual package (*4)

Type of medical device	Product code	Expiration date	Lot number or serial number
Specially controlled medical device, etc (*5) (including specially designated maintenance management required medical device)			
Designated insured medical material			
Medical devices other than the above			
In vitro diagnostics			

Marking on inside box (*6) and outside box (*7)

Type of medical device	Product code	Expiration date	Lot number or serial number
Specially controlled medical device, etc (including specially designated maintenance management required medical device)			
Designated insured medical material			
Medical devices other than the above			
In vitro diagnostics			

2) Consumable Supplies other than Medical Devices (*8)

Marking subjects are consumable supplies other than medical devices which are repeatedly used entirely at medical institutions. Product code, expiration date and lot number should be placed on the inside box and outside box as shown in the following table.

Packaging unit	Product code	Expiration date	Lot number
Inside box and outside box			

(*1) "Medical devices" refers to the medical devices as stipulated in Article 2, Paragraph 4 of the Pharmaceutical Affairs Law. Any medical devices, etc used entirely in the home (including contact lens) are exempt from the marking requirement. "In vitro diagnostics" refers to the in vitro diagnostics as stipulated in Article 2, Paragraph 13 of the Pharmaceutical Affairs Law.

- (*2) State the final expiration date for the use of the medical device, etc. (State the date in YYMMDD format – ISO-8601 format. Provide the lower two digits of the calendar year, and two digits each for the month and day. If the expiration date does not include the day, then use “00” for the day.) This applies only to those for which sterilization expiration period or expiration period due to chronological change exists.
 “Usable life” of a durable medical device is not required to mark.
- (*3) “ ” means marking is necessarily required (indispensable marking), “ ” means marking is left to the discretion of the company (voluntary marking).
- (*4) Individual package refers to the package, out of the packages used, that contains the smallest unit of the product, and that directly contains the product.
 However, barcode marking is voluntary for those of which individual package is not the smallest unit of sales (document attached unit) except for “designated insured medical material”.
- (*5) Within the category of the specially designated maintenance management required medical device, marking on individual package is voluntary for large medical devices such as the installation-controlled medical device (i.e. “Installation-controlled medical device” stipulated in Article 93, Paragraph 1 of the Enforcement Order of the Pharmaceutical Affairs Law).
- (*6) Inside box refers to the package that packages or contains a fixed quantity (does not change on order) of individual packages of the same product.
- (*7) Outside box refers to the package that packages or contains a fixed quantity (does not change on order) of inside boxes of the same product.
- (*8) Out of the consumable supplies other than medical devices, pharmaceuticals for medical use are not subject to the guidelines.
- (*9) Samples are exempt from barcode marking. As for clinical study medical devices, barcode marking is required.

2. Setting of Product Codes

The product codes should be internationally harmonized standards. Above all, the product codes of GS1 (*10) (i.e. JAN code and GTIN-13 / GTIN-12 that is acquired in overseas, hereinafter referred to as “JAN Codes, etc.”) that have been familiarized and used in Japan are recommended to use. In this occasion, the placed code should be a 14-digit code beginning “0” followed by JAN code, etc. in the case of individual package, and beginning “indicator” followed by JAN code, etc. in the case of outside box and inside box. However, if a JAN code, etc. on the outside box or the inside box is different from that of the individual package, beginning number is to be “0”.

- (*10) GS1 is an organization which was renamed from EAN International after the Uniform Code Council had been unified with it. JAN code widely used in Japan is managed by GS1 as the international product code.

3. Barcode Symbol

It is recommended to use JIS X 0504 (Barcode Symbol – Code 128 – Basic Specification) as barcode symbol. If the space is too small for the barcode, a 2-dimensional symbol standardized by ISO can be used.

4. Registration in Medical Device Database

As it is necessary to consistently manage and utilize the information displayed by codes, the licensed marketing approval holders of medical devices and in vitro diagnostics and the manufacturers, etc. of consumable supplies should register the information of the products with barcode marking when shipping them in a medical device database which is open to the public.

5. Date of the enforcement of Barcode Marking

The designated insured medical material is subject to the marking requirement from all those shipped by the licensed marketing approval holders in or after March, 2009. Out of the designated insured materials, orthopedic implant products (unsterilized products such as osteosynthesis products) on which it is difficult to place barcodes given the current technology, are, however, exempt from the marking requirement until the transition to sterilization is completed, upon which barcodes should be promptly placed on the products.

Out of medical devices, the specially designated maintenance management required medical device and the specially controlled medical device excluding above, are subject to the marking requirement from all those shipped by the licensed marketing approval holders in or after March, 2010.

The medical devices excluding and above and the consumable supplies other than medical devices are subject to the marking requirement from all those shipped by the licensed marketing approval holders and manufacturers in or after March, 2011.

The in vitro diagnostics are subject to the marking requirement from all those shipped by the licensed marketing approval holders in or after March, 2009.

6. Notes on Barcode Marking

Marking on the product body surface is not required by these guidelines, however it will be examined in the future taking into consideration international harmonization, technology development and its verification, etc.

As for the data that are left to the discretion of companies (voluntary marking), expansion of the scope of marking shall be considered in the future by studying how such data are actually displayed and used.