Report on the Status of UDI in Japan

The Japan Federation of Medical Devices Associations

UDI Committee

July 3, 2018

1. Developments of UDI in Japan

Developments of UDI, on Japanese and International Levels

2010
UDI is examined by the GHTF.

Sept. 2013
U.S. FDA issues UDI regulations.

Dec. 2013
IMDRF
UDI guidance is issued.

May 2017
EU
MDR IVDR regulations are issued.

2018

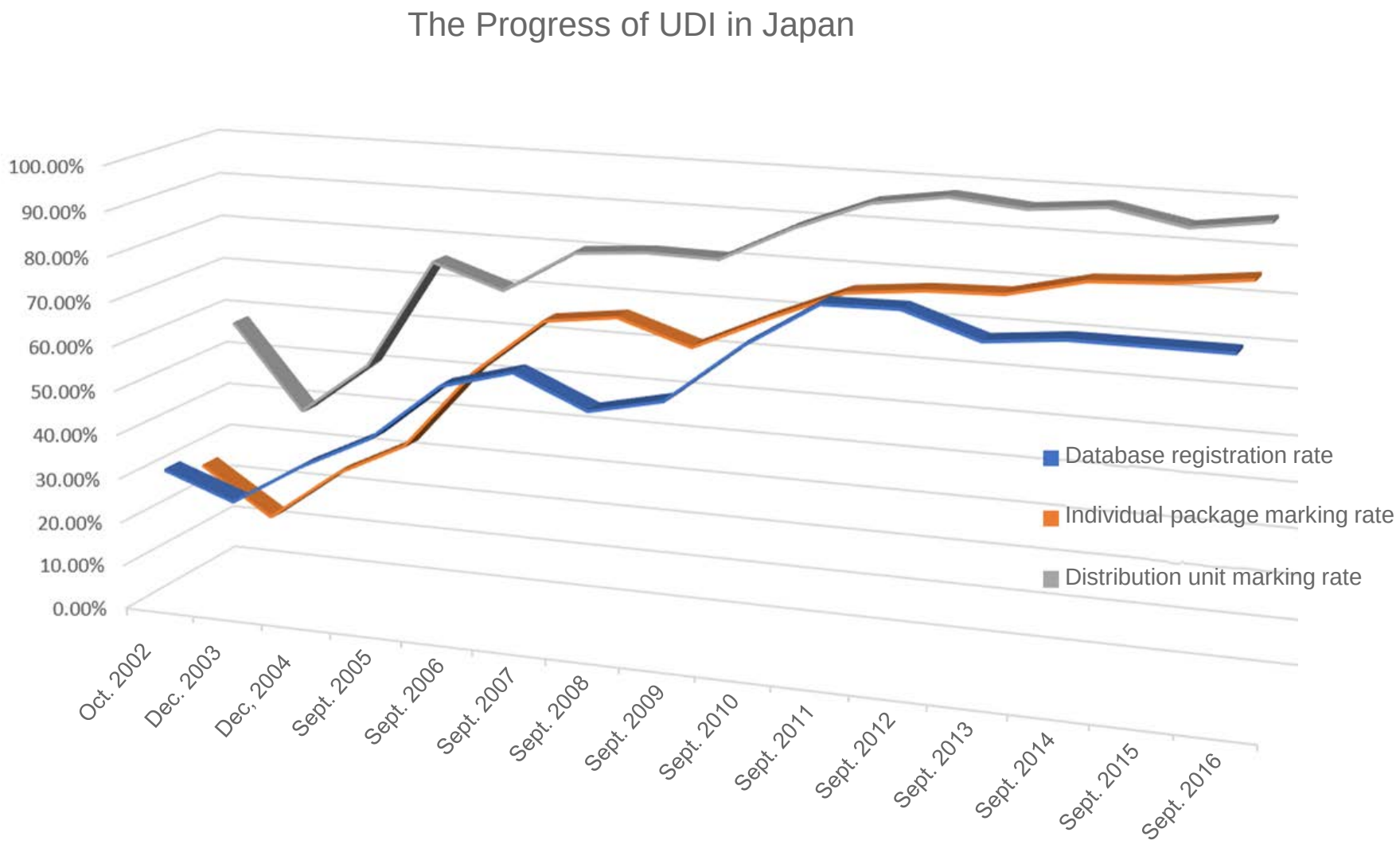
March 1999
Introduction of EAN-128 is decided.

Dec. 2000
The MEDIS-DC database is built.

March 2008
• Director, Economic Affairs Div., MHLW notification "Barcode marking and database registration"
• The JFMDA manual is revised.

March 2016
The latest UDI operation manual is issued, based on the IMDRF UDI guidance.

The Progress of UDI in Japan



Issues Involving UDI Progress

- The database registration rate
  has not improved from the 77% level,
  > Limitation of notification-based operation?
- The individual package barcode marking rate
  remains around the 88% level.
  > Limitation of GS1-128 marking
- The distribution unit barcode marking rate
  is at a feasible level of the 96% level.

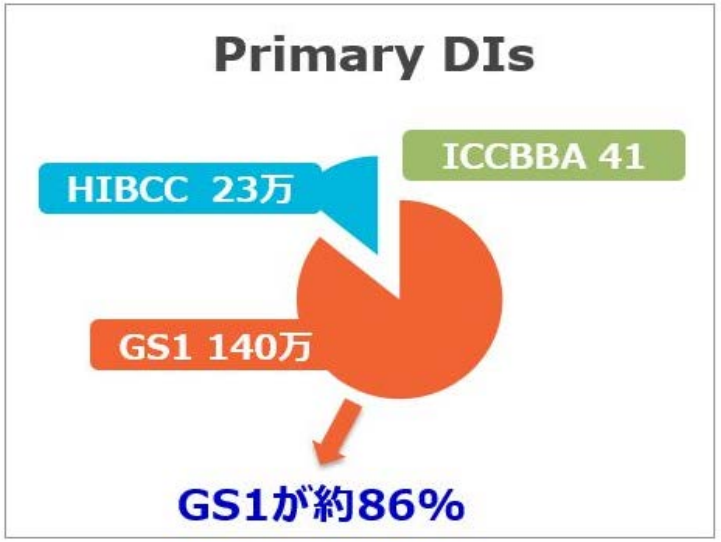
Comparison of the Number of Data Items U.S. Data

UDI Status in the United States (1)

(Presenter: Ms. Sigg, FDA)

◆ GUDID (Global Unique Device Identification Database)

- The number of registered items has exceeded 1.6 million. (as of April 2, 2018)
- GS1 accounts for the greatest number of registered primary DI items by issuing body.



Source: GS1 Healthcare Japan Council

Comparison of the Number of Data Items Japan Data

May 17, 2018

Report from MEDIS

1. Status of the Medical Device Database

(1) Registration Status Total registration number	(as of May 10) 1,026,334 items (688 companies)	(as of March 5) 1,029,525 items (680 companies)
Machinery	22,15] items (332 companies)	22,019 items (329 companies)
Devices in general	910,281 items (550 companies)	914,21 items (544 companies)
0. Unredeemable	607,632 items (508 companies)	607,756 items (504 companies)
1. Insurance reimbursement	294,320 items (239 companies)	298,680 items (238 companies)
2. Purchase price	1,041 items (4 companies)	1,041 items (4 companies)
3. Intraocular lens	5,708 items (7 companies)	5,669 items (7 companies)
4. Specific medical fee calculation	1,580 items (19 companies)	1,575 items (19 companies)
No. of items of 1–4 above	302,649 items (269 companies)	306,965 items (268 companies)
In vitro diagnosis	12,328 items (81 companies)	12,146 items (81 companies)
Other	81,574 items (283 companies)	80,639 items (283 companies)

Comparison of the Number of Data Items

- The number of MEDIS-DC data items: approx. 1 million
  Too small compared with 1.6 million in the U.S.?

- The number of items reported to the MEDIS-DC is GTIN-13.

- The actual number represents GTIN; if about half of these items have an inner box, the number amounts to 1.5 million.
  At the GTIN level, the number is assumed to be equivalent to 2 million.

2. Operation of UDI in Japan

UDI Guidelines in Japan

2010
UDI is examined by the GHTF.

Sept. 2013
FDA issues UDI regulations.

Dec. 2013
IMDRF
UDI guidance is issued.

May 2017
EU
MDR IVDR regulations are issued.

2018

March 1999
Introduction of EAN-128 is decided.

Dec. 2000
The MEDIS-DC database is built.

March 2008
• Director, Economic Affairs Div., MHLW notification "Barcode marking and database registration"
• The JFMDA manual is revised.

March 2016
The latest UDI operation manual is issued, based on the IMDRF UDI guidance.

The Scope of Notifications Issued in 2008

	Direct marking on the product body		Marking on individual package (Note 4)			Marking on inner box/outer box		
	Product code	Lot No. or serial No.	Product code	Validity/ expiration date	Lot No. or serial No.	Product code	Validity/ expiration date	Lot No. or serial No.
Specially controlled medical devices (Note 5) (Including specific maintenance management medical devices)			◎	◎	◎	◎	◎	◎
Special Treatment Materials			◎	◎	◎	◎	◎	◎
Medical devices other than those described above			◎	○	○	◎	◎	◎
In vitro diagnostics			◎	◎	◎	◎	◎	◎
Consumable materials other than medical devices			○	○	○	◎	○	○

(Note 4) The “individual package” refers to the smallest unit of an item’s packaging, which packages the content directly.
However, except Special Treatment Materials, **the barcode marking shall be made optional for items whose unit of the individual package is not the smallest sales unit (the unit of package insert).**

(Note 5) Of the specific maintenance management medical devices, for large medical devices, such as “installation controlled medical devices” (specified in Paragraph 1, Article 93, Ordinance for Enforcement of the Pharmaceutical Affairs Act), **the individual package marking shall be made optional**.

6. Points to Note Regarding Barcode Marking

(1) Although marking the barcode **directly on the body of medical devices** is outside the scope this time, it will be examined in the future, based on international harmonization, technology development, and the verification of such technology, etc.

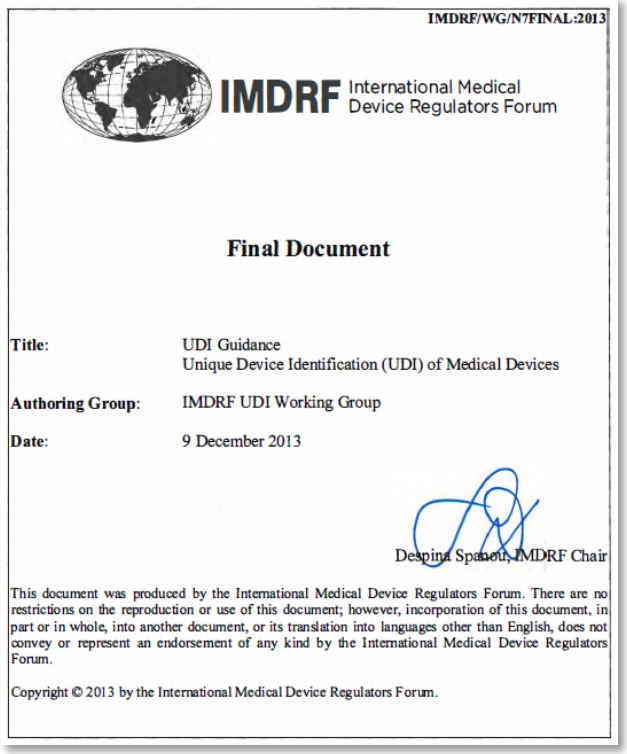
(2) Regarding data left to each company's voluntary decision (**optional marking**), a subsequent expansion of the scope of marking shall be examined, based on the status of marking and usage in the future.

International Guidelines for UDI Operation

The International Medical Device Regulators Forum (IMDRF) issued the Medical Device UDI Guidance in December 2013.

The current members are

- Australia
- Brazil
- Canada
- China
- Europe
- Japan
- Russia
- Singapore
- South Korea
- USA



IMDRF/WG/N7FINAL:2013

IMDRF International Medical Device Regulators Forum

Final Document

Title:	UDI Guidance Unique Device Identification (UDI) of Medical Devices
Authoring Group:	IMDRF UDI Working Group
Date:	9 December 2013

Despina Spanou, IMDRF Chair

This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the International Medical Device Regulators Forum.

The Purport of the IMDRF UDI Guidance

a. traceability of medical devices, especially for field safety corrective actions,

b. adequate identification of medical devices through distribution and use,

c. identification of medical devices in adverse events,

d. reduction of medical errors,

e. documenting and longitudinal capture of data on medical devices.

IMDRF Guidance Documents

IMDRF/WG/N7FINAL:2013

11. Annex

Category	Unpacked UoU → Direct Part Marking (DPM)	Base Package	Bulk Package Higher package configuration	Remarks
Single-use MD				
• IMDRF class A (low-risk)	-	-	DI + PI	• Flexibility on possible exemption for PI
• IMDRF class B (medium-r.)	-	-	DI + PI	
• IMDRF classes C+D (high-r.)	-	DI + PI	DI + PI	
Reusable MD				• Require reprocessing between uses
• All risk-classes	DI + PI	DI + PI	DI + PI	• Not all package levels necessarily exist, e.g.: surgical instruments, intravenous (IV) infusion pumps.
Implantable MD				• PI = Serial number for active implants
• Sterile	-	DI + PI	DI + PI	• Usually single packed (1 piece)
• Non-sterile	Must be identifiable	DI + PI	DI + PI	• Often multiple packed ("n" pieces) • Not necessarily DPM, other technological options allowed to identify the unpacked MD
Others				
• Kits (IVD / non-IVD)	-	DI + PI	DI + PI	• Concerns the kit package itself
• SaMD	DI + PI	DI + PI	-	• Must not necessarily be packed
• Configurable MD Systems	DI + PI	-		• AIDC carrier to be placed on a ‚main part' (primary mode of action)
• OTC exclusively	-	-	DI (linear bar code)	• Point-of-Sale scanners can't work with PI
• OTC + other channels	-	-	DI + PI (non-concatenated)	• PI should be presented in a separate AIDC carrier due to Point-of-Sale scanners

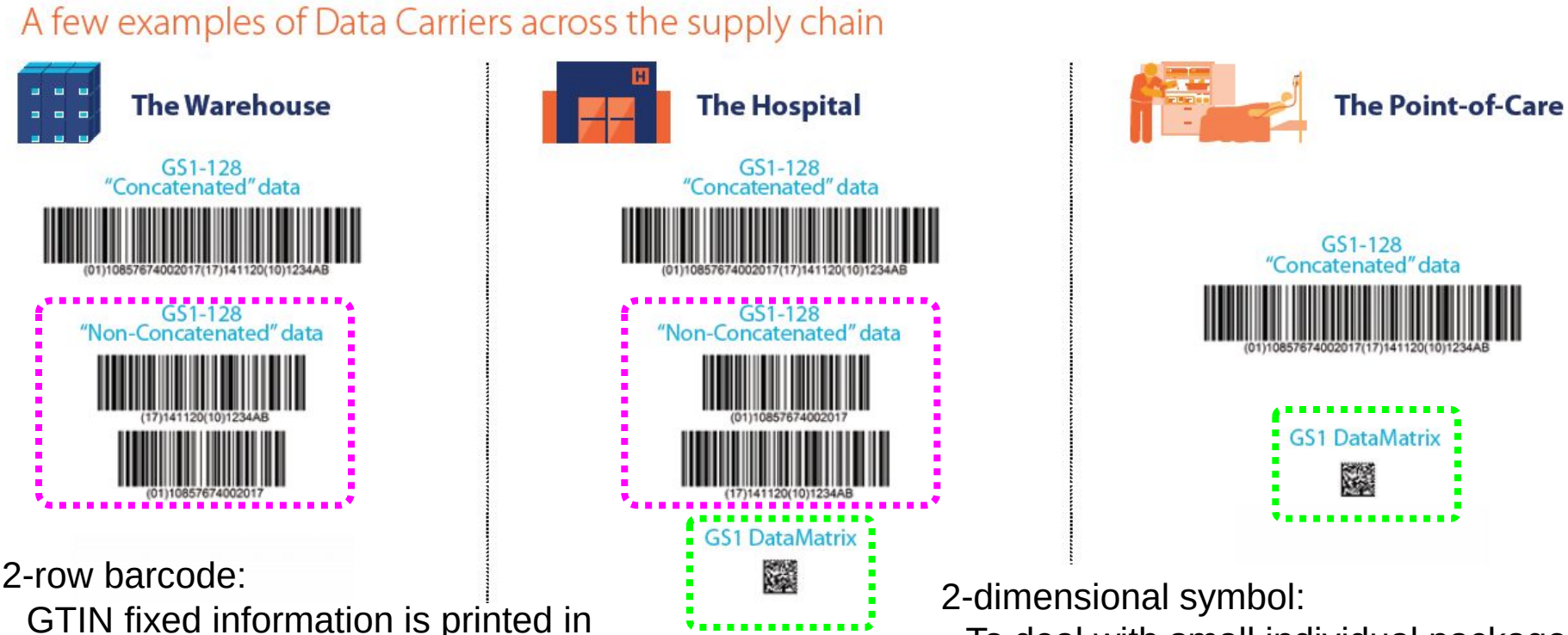
Differences from the IMDRF Guidance

	Direct marking on the product body		Marking on the individual package (Note 4)			Marking on the inner box/outer box		
	Product code	Lot No. or serial No.	Product code	Validity/ expiration date	Lot No. or serial No.	Product code	Validity/ expiration date	Lot No. or serial No.
Specially controlled medical devices (Note 5) (Including specific maintenance management medical devices)			◎	◎	◎	◎	◎	◎
Special Treatment Materials			◎	◎	◎	◎	◎	◎
Medical devices other than those described above			◎	○	○	◎	◎	◎
In vitro diagnostics			◎	◎	◎	◎	◎	◎
Consumable materials other than medical devices			○	○	○	◎	○	○

We will prepare for international harmonization through voluntary initiatives in the scope of optional individual package marking, marking on the product, direct marking on the product body.

Background of International Harmonization

GS1 Healthcare materials



2-row barcode:
GTIN fixed information is printed in advance in some cases.

2-dimensional symbol:
To deal with small individual packages

We need to accept and work with the 2-row barcode and 2-dimensional symbol.

The Positioning of the JFMDA Manual

IMDRF International Medical Device Regulators Forum

Complies with international operation guidelines
- The scope of UDI marking
- UDI marking methods, information content

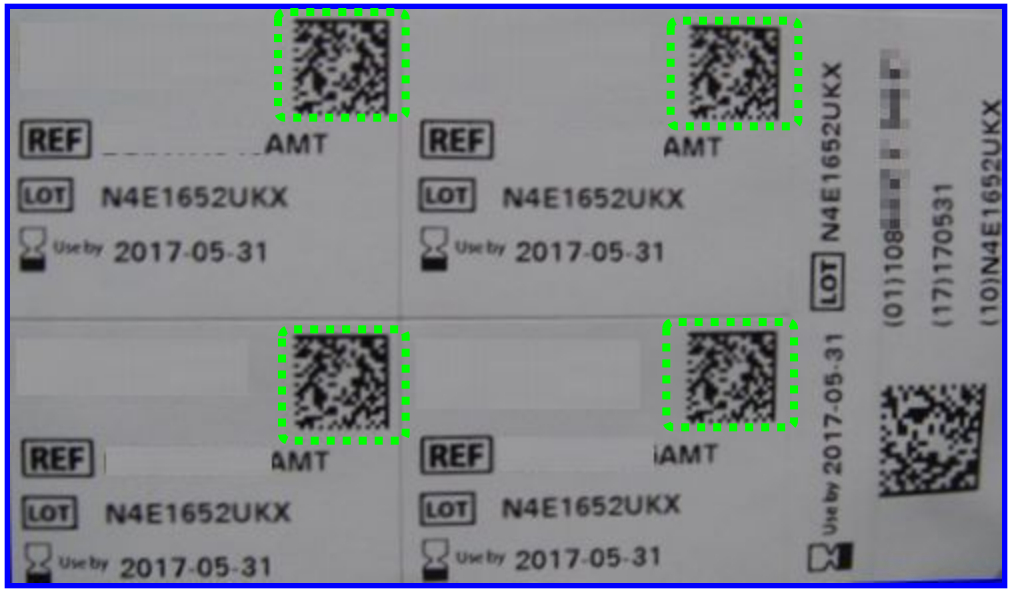
GS1 The Global Language of Business

Adopted international standard specifications
- Product identification code
- AIDC-compliant specifications

Initiatives for International Harmonization

1. Promoting Marking on the Product and Direct Marking Direct on the Product Body
   - Marking on medical devices that are used repeatedly after washing, disinfection, and sterilization.
   - Marking on the body of portable medical devices
2. Promoting Marking on Individual Packages
   - Marking on individual packages of products below the sales unit
   - The GS1 data matrix is used for marking on individual packages on which GS1-128 barcode marking is difficult.
3. Initiatives for International Harmonization
   - Acceptance of the GS1-128/GS1 data matrix on products manufactured overseas

Examples of Individual Package Marking on UDI-Compliant Products in the USA



Since over-labeling is impossible after importing, such marking will be used as is. It is also impossible to work on direct markings on the product body of medical devices after manufacturing.

Operation Based on International Harmonization

Imports:

- When the barcode of the overseas manufacturer of the product is GS1 and its necessary manufacturing information is included, the product can be distributed in Japan as is.

- The GS1 standard GTIN can be operated in Japan as is; it is not necessary to have a new GS1 operator code provided from the MEDIS-DC (GS1 Japan) and set a GTIN-13 (JAN) starting with 49 or 45.
  It is possible to obtain a GTIN-13 from GTIN, and operate it in Japan, as with JAN.

Exports:

- It is possible to export products using GTIN generated with a GTIN-13 (JAN) starting with 49 or 45.

Thank you for your attention.