Barcode Marking on Medical Devices in Japan

Feb.13,2008

Chairman of IT Committee

JFMDA
Shuichi Harayama

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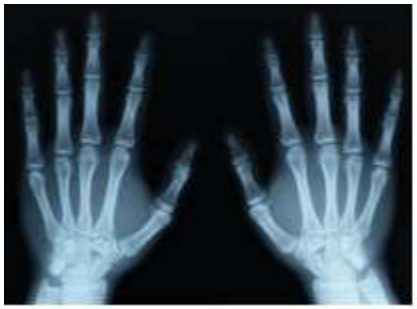
1. IT Committee of JFMDA and its Activities
2. IT Infrastructure for Medical Device Industry in Japan
3. Factors for success in standardization
4. Guidelines of MHLW harmonized with GS1 Standards
5. JFMDA supports and promotes GS1 Standards



DO YOU KNOW “IKIREN” ?

医機連
日本医療機器産業連合会
JFMDA
The Japan Federation of
Medical Devices Associations

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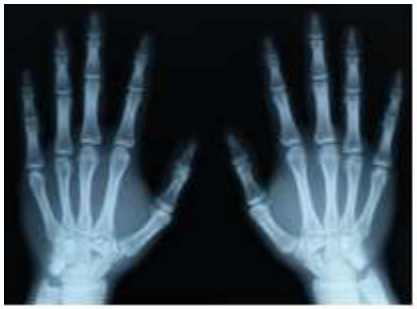


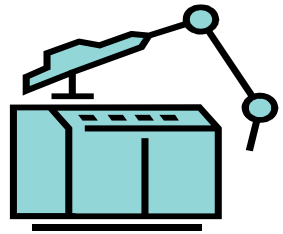
1-1. Outline of JFMDA

JFMDA : The Japan Federation of Medical Devices Associations

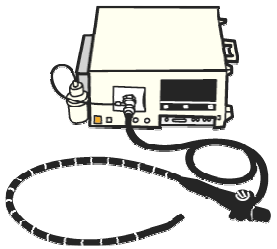
- **Established in February, 1984**
- **Composed of 20 associations of medical devices manufacturers and sales agents in Japan**
- **Total number of affiliated companies : around 4800**

  3500 manufacturers

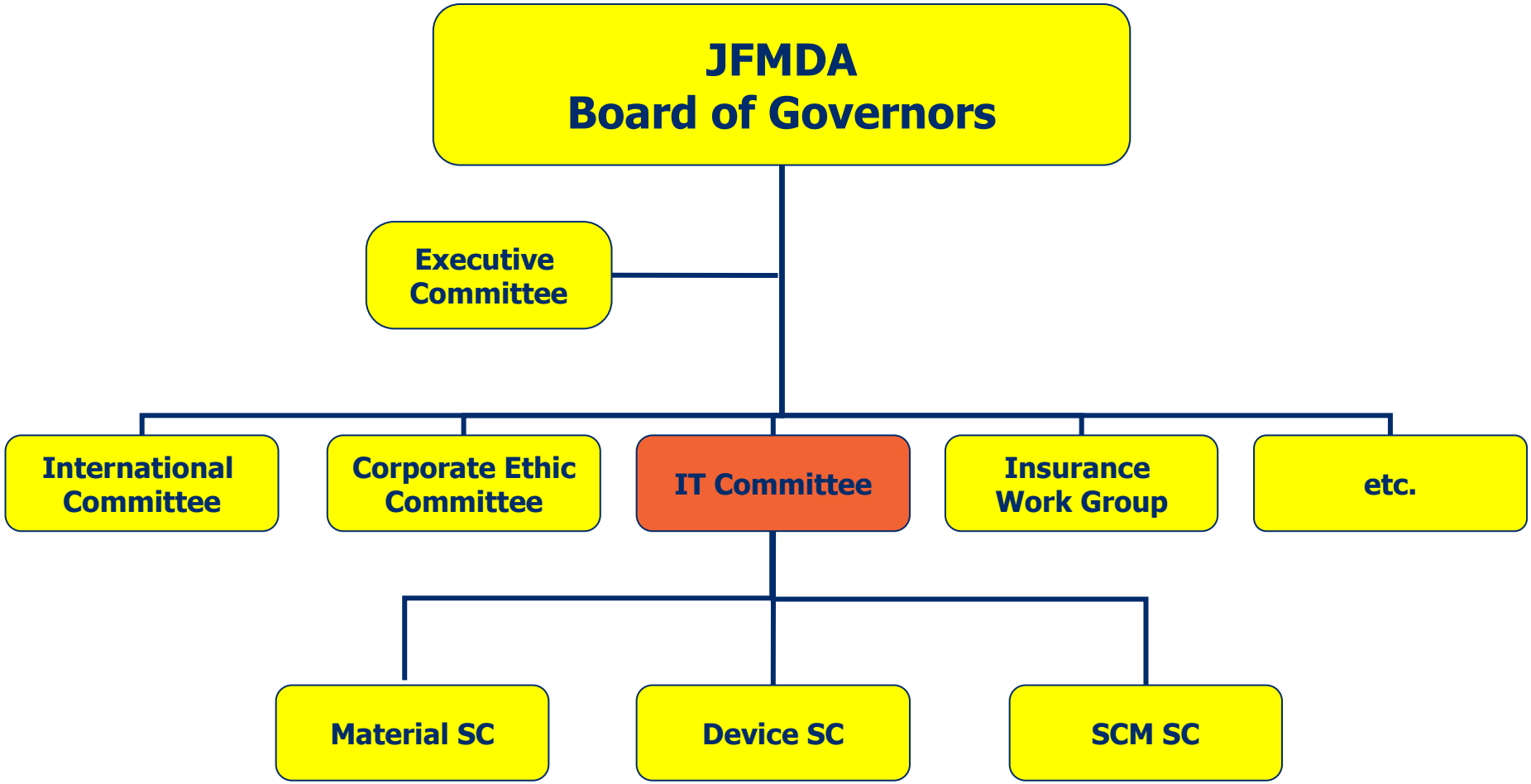
  1300 sales agents (including wholesalers)



- **18 Committees/Work Groups, Broad activities**
- **IT Committee has promoted standardization and promotion of product codes, barcodes and electronic commerce for medical devices & materials from 1995 in cooperation with GS1 Japan**



1-2. IT Committee of JFMDA



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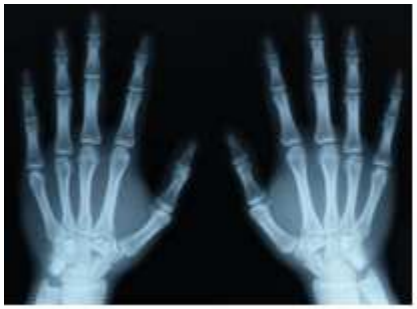
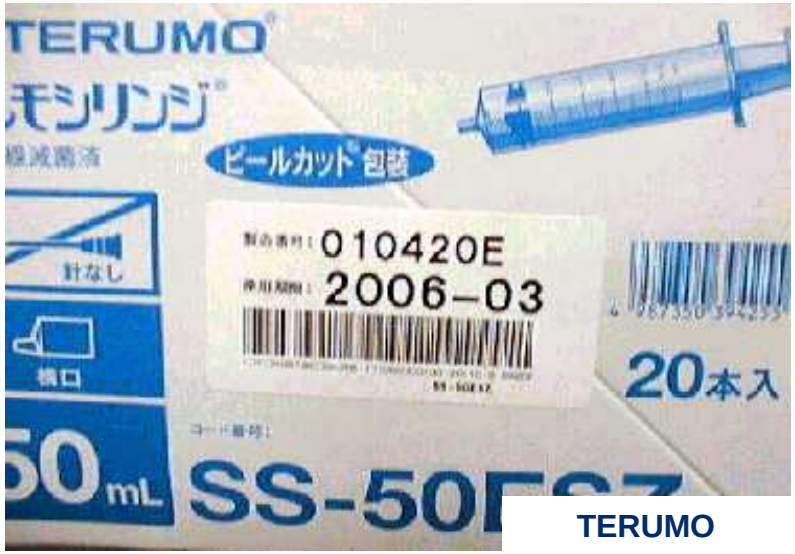


2-1. Advanced IT Infrastructure

Results of the efforts to make Advanced IT Infrastructure・・・

1. More than 70% of the Products wears Barcode (GS1-128)
2. More than 510,000 Items are registered in the public Data Base (MEDIS-DC)
3. Around 85 Million transactions per year through the ordering network

2-2. Examples of Marking G S 1-128 Barcode



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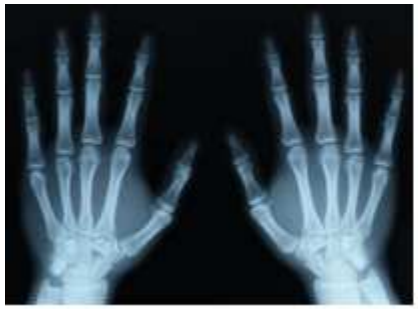


3-1. Standardization Activities of JFMDA

Consulting with MHLW on standardization of product codes for medical devices from 1998

JFMDA has been making efforts …

Mar. 1999 ; to issue Guidelines for Standardizing Product Codes for Medical Materials in Japan

July 2002 ; to issue GL for Individual Packaging of Medical Materials

Sep. 2005 ; to issue 5th ed. of Manual for GL for Standardizing Product Codes

Dec. 2006 ; to issue Revised 5th ed. of Manual for GL for Standardizing Product Codes

3-2 . Cooperation with MHLW

Mar. 1999 ; JFMDA issued GL for Standardizing Product Codes for Medical Materials

Support from the Ministry of Health, Labour and Welfare

Dec. 2000; to begin establishing Medical Material Data Base

Dec. 2001; to announce Grand Design for IT Utilization in Insured Medical Services

Oct. 2002; to begin IT infrastructure survey in medical device industry

Jun. 2007; 3-year Plan for the Promotion of Regulatory Reform" decided by the cabinet

Mar.? 2008; to issue notification of GL for Bar Coding on Medical Devices

3-3 . Important Factor for Success in Standardization

Mar. 1999 ; JFMDA issued GL for Standardizing Product Codes for Medical Materials

Support from the Ministry of Health, Labour and Welfare

Dec. 2000; to begin establishing Medical Material Data Base

Dec. 2001; to announce Grand Design for IT Utilization in

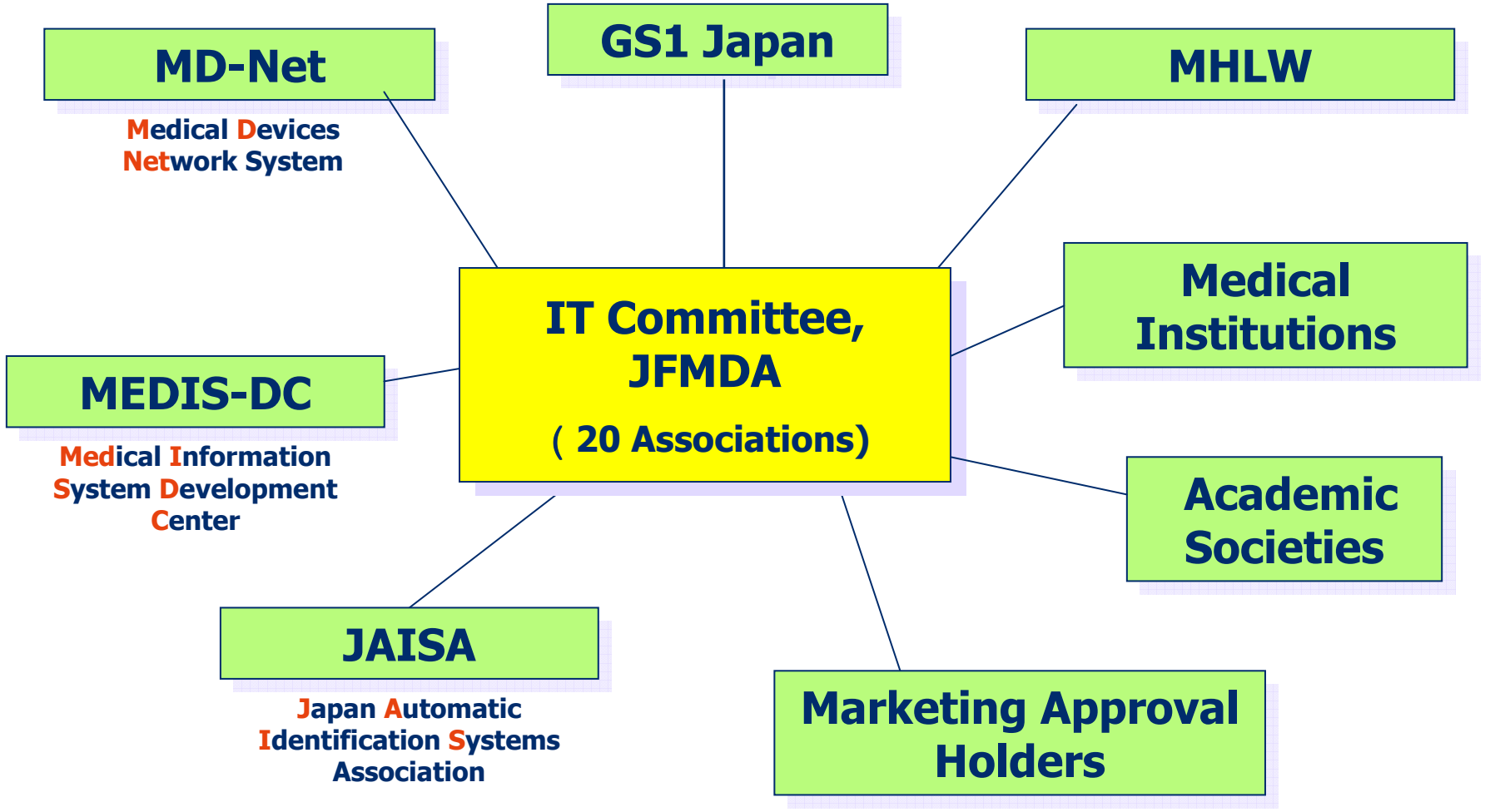
Oct. 2002 to begin IT infrastructure survey in medical

Jun. 2007; 3-year Plan for the Promotion of Regulatory Reform" decided by the cabinet

Industry Associations & the Administration cooperatively working on standardization!

Mar.? 2008; to issue notification of GL for Bar Coding on Medical Devices

3-4 . IT Committee & Relating Organizations



JFMDA awarded a prize from GS1 Japan

JFMDA was awarded a prize from GS1 Japan for its standardizing activities in Jan. 2007.

Ms. Sakamoto (President of GS1 Japan) and Harayama (myself)

3-5．Rate of Barcoding exceeds 70%

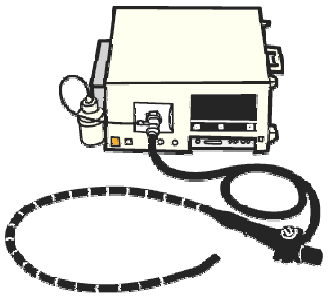
	As of 30 September 2006			(Comparison: As of 30 Sep. 2005)
	(Medical materials)	(Medical device)	(total)	
Number of Items	482,369	129,463	611,832	536,660
Number of Items with GTIN-13	449,068 (93.1%)	100,932 (78.0%)	550,000 (89.9%)	470,353 (87.6%)
Number of Items Registered to MEDIS-DC Database	313,029 (64.9%)	31,350 (24.2%)	344,379 (56.3%)	232,583 (43.3%)
Number of Barcoding Items	369,380 (76.6%)	60,117 (46.4%)	**429,497 (70.2%)**	380,029 (70.8%)
Number of Items of which Smallest Package (could be unit of use) barcoding	267,259 (55.4%)	—	—	168,966 (31.5%)

Survey sent to：**540 companies** belong to JFMDA(manufacturers and distributors) or its member associations． Answer received from：**476 companies** (88.1% of recipients)

3-6 . No. of Items registered in the public Data Base exceeds 500000

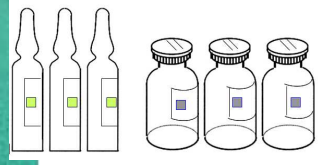
Items registered in MEDIS-DC Data Base （as of Jan. 25, 2008 ）

Total No. of registered Items ; 518,258



Medical Equipments ; 8,442

Medical Apparatus ; 4

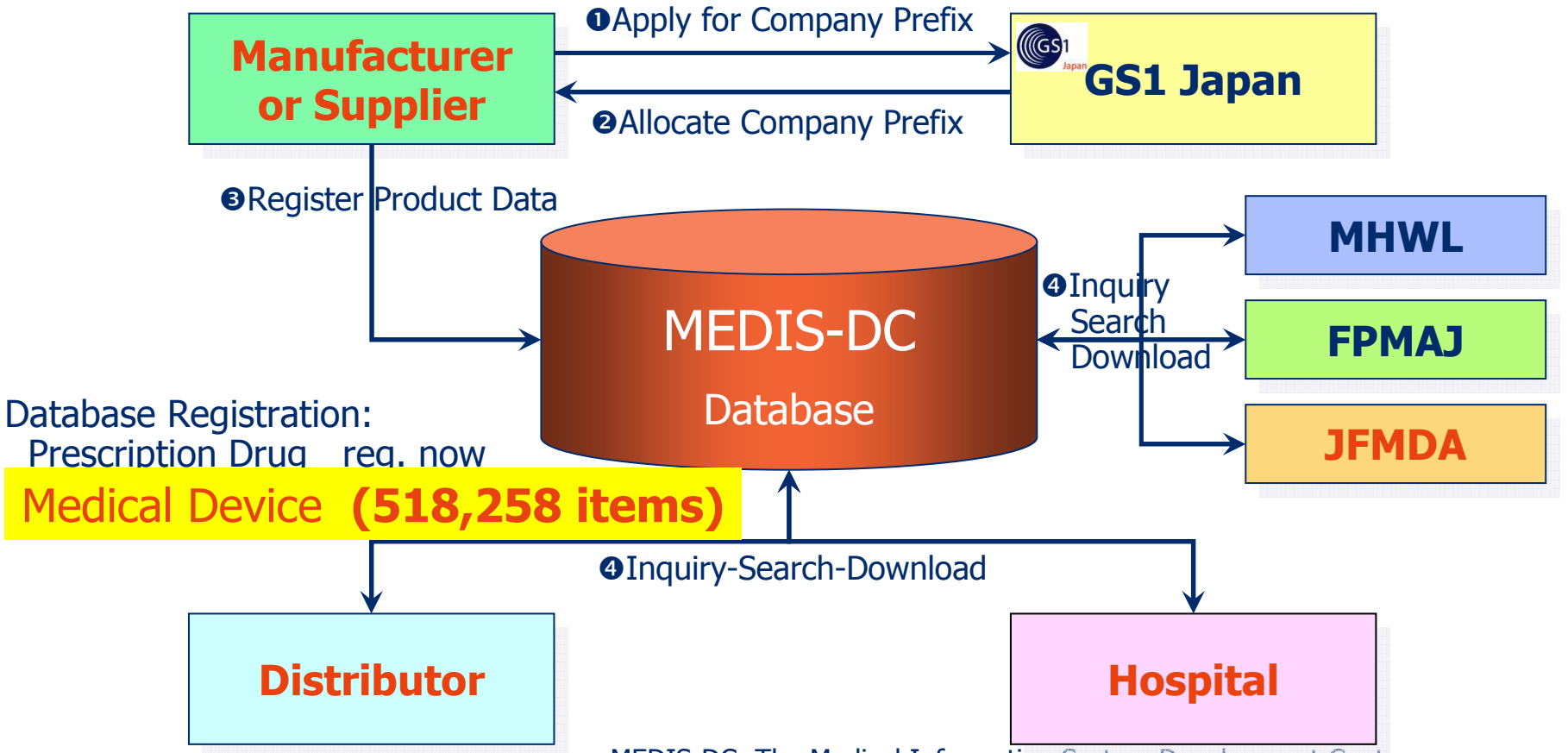


In vitro Diagnostics ; 3,514

Miscellaneous ; 42,984

3-7 . Healthcare Products Database

GS1 Company Prefix:
Prescription Drug approx 100%
Medical Device approx 89.9%



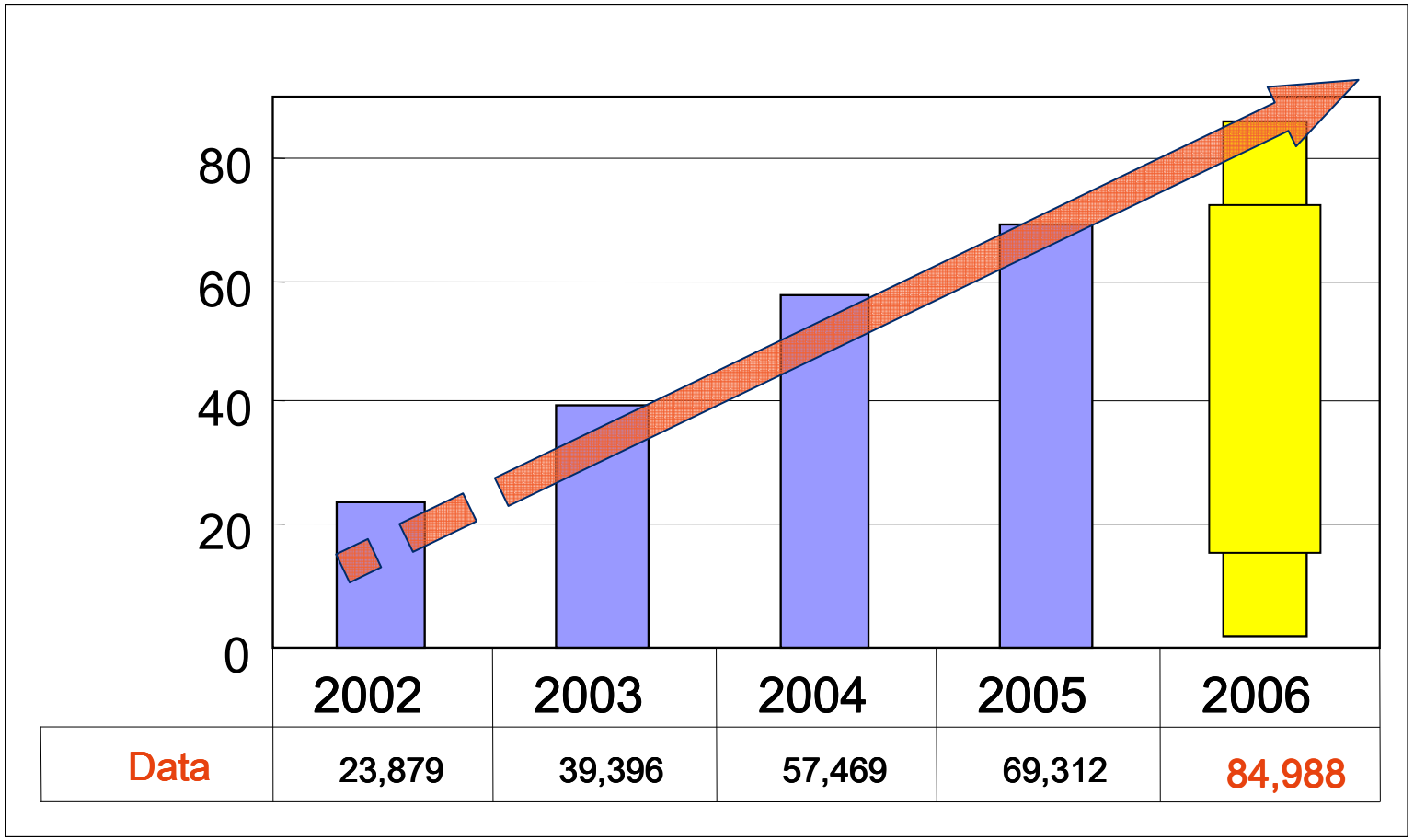
Database Registration:
Prescription Drug reg. now
Medical Device **(518,258 items)**

Survey : 2 5 Jan. 200 8

MEDIS-DC: The Medical Information System Development Center
MHLW : Ministry of Health, Labour & Welfare
JFMDA : The Japan Federation of Medical Devices Associations
FPMAJ :The Federation of Pharmaceutical Manufacturers' Associations of Japan

3-8 . Around 85 million orders per year through MD-Network

Number of transactions per year through the Network (unit ; 1000)



	2002	2003	2004	2005	2006
Data	23,879	39,396	57,469	69,312	84,988

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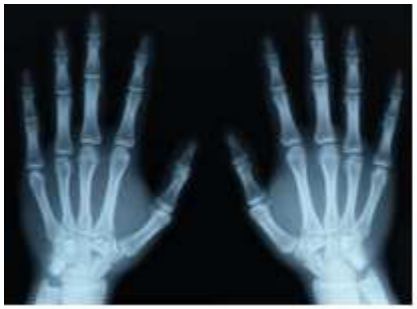


4-1 . Background of a notification for Barcode Marking by MHLW

"3-Year Plan for the Promotion of Regulatory Reform" decided by the cabinet on June 22, 2007

- **Promotion of placing standard codes on pharmaceuticals and Medical Materials (to take action by the end of 2007fy)**

  …Concerning Pharmaceuticals, the notification has already been issued, …as for Medical Materials, a notification for placing standard codes should be issued as well….

4-2 . MHLW Draft Guidelines for Barcode Marking on Medical Devices

Outline of revised MHLW Draft Guidelines for Barcode Marking

Objective

Promotion of efficient distribution systems & medical administration, securing traceability and prevention of medical accidents

Contents

1. **Marking Subjects and Data to be Placed – Medical Devices, in vitro diagnostics and consumable Supplies**
2. **Setting of Product Codes – GTIN recommended**
3. **Barcode Symbol – Code 128 recommended**
4. **Registration in Medical Device Database**
5. **Date of the enforcement of Barcode Marking – 1 to 3 years after the issuance of notification**
6. **Notes on Barcode Marking**

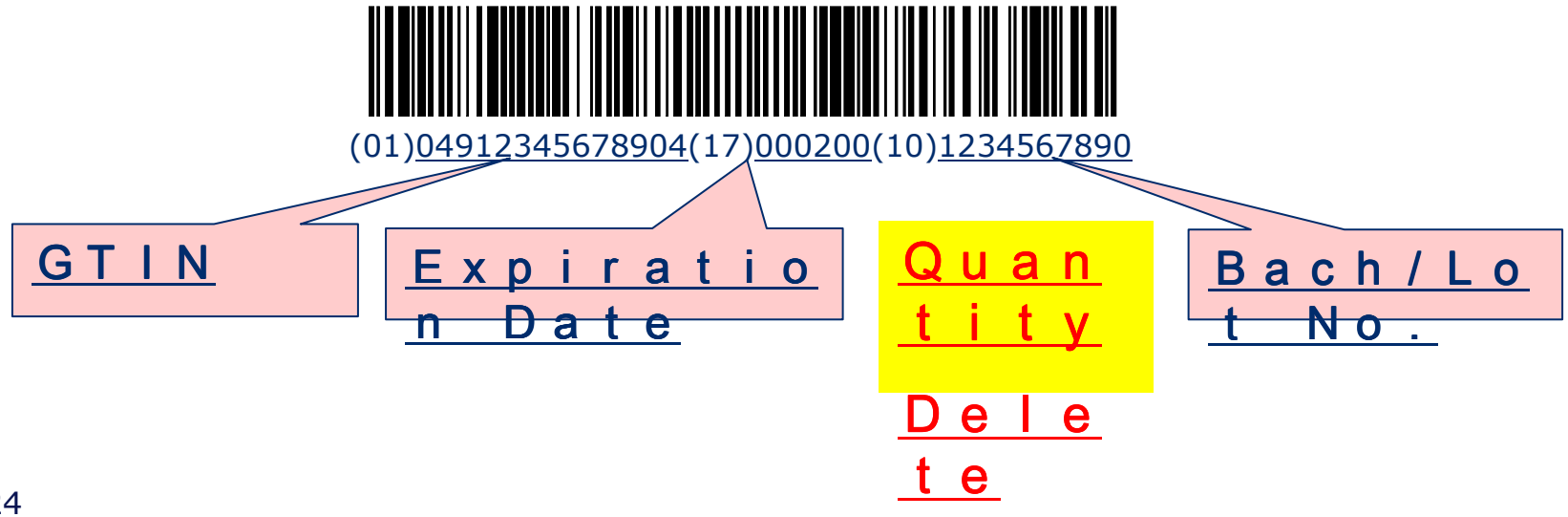
4-3 . Points of MHLW's Notification (Barcode Guidelines)

1. Not a legal regulation (not mandatory)
2. to promote JFMDA's Guidelines
   - History of 9 years since 1 9 9 9
3. Guidelines for marking on the package of medical devices
   - Marking on product body is not yet required
4. Harmonized with GS1 standards
5. to promote the registration in a public Data Base
   - To make manufacturers aware of the Data Base to promote the registration

Major revisions from the original draft upon public comments

1. Revisions for the harmonization with GS1 Standards

- **to delete AI(30) from marking requirement**



4-5. MHLW Guidelines are harmonized with GS1 Standards (Cont.)

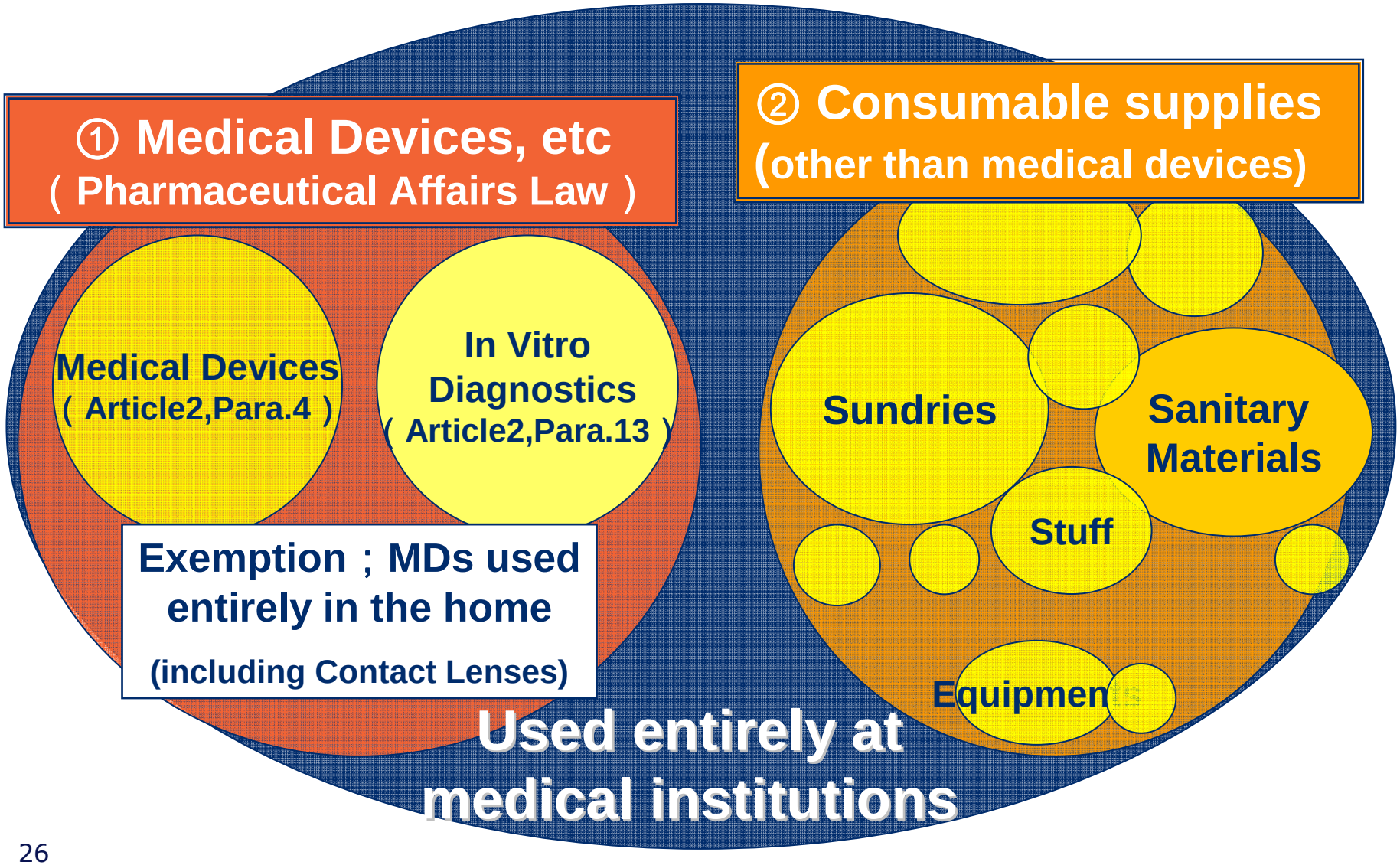
- to recommend the use of GTIN explicitly as product codes

  GTIN-13/12 *YES!!*
- to delete the order of the data elements
- to harmonize the use of indicator in the first digit of product code

2. to delete Marking on the Product Body

Marking on the product body will be examined in the future because strong needs exists among healthcare providers and research institutions

4-6 . Scope of Marking = ①+②

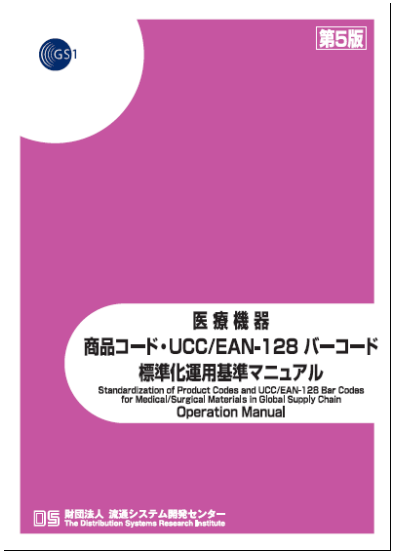


4-7. History of Guidelines for Barcode Marking

Guidelines for Standardizing Product Codes & Barcodes for Medical/Surgical Materials in Japan

by JFMDA (The Japan Federation of Medical Devices Associations)

1999		Released
2000		Manual for the Guidelines (ver. 1)
2002		Manual for the Guidelines (ver. 4)
2005		Manual for the Guidelines (ver. 5) GS1 DataBar option was added.
2007	Sept.	MHLW invited public comments on the draft Guidelines.
	Oct.	GS1 HUG and GS1 Japan submitted comments.
2008	Mar.	MHLW is expected to issue Notification.

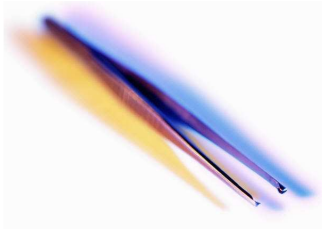


Manual (ver. 5)

Notification for Bar Coding on Medical Devices

by MHLW (Ministry of Health, Labour and Welfare)

4-8. 2-D Direct Part Marking on Metal Apparatus



Guideline:
drafted by JAMEI (Japan Association of Medical Equipment Industries) in October 2006
Guideline issued November 2006

Objectives: Patient safety, Traceability/Recall & Asset Management

Metal Apparatus:
Made of stainless, aluminum, copper alloy, titanium, ceramics, etc.
Used for operation, medical treatment, etc.

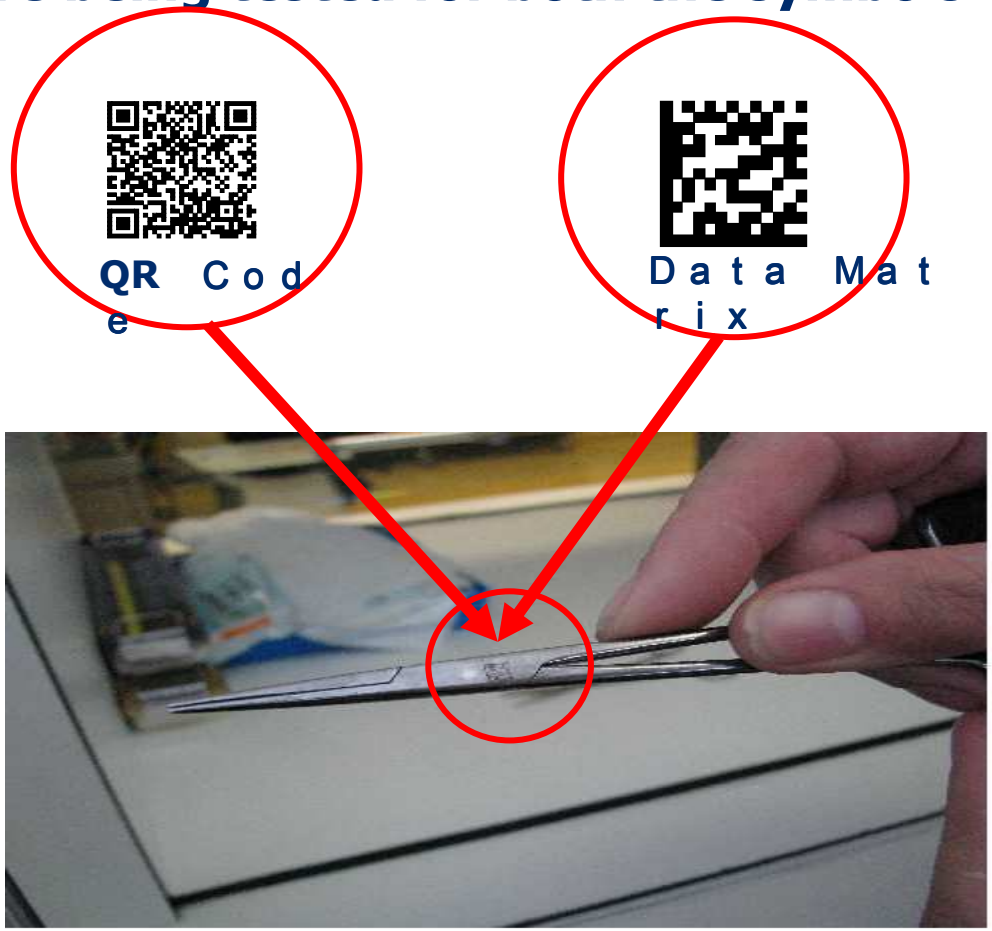
Symbol: Data Matrix (ISO/IEC 16023) ECC 200
or QR Code (ISO/IEC 18004)

Two symbols !

Data : AI (01) 14 digits GTIN
AI (21) 8 digits Serial No.

4-9. Two dimensional symbol on Metal Apparatus

JAMEI is testing symbol quality and reading performance are being tested for both the symbols



2-D Scanner

2-D Scanner

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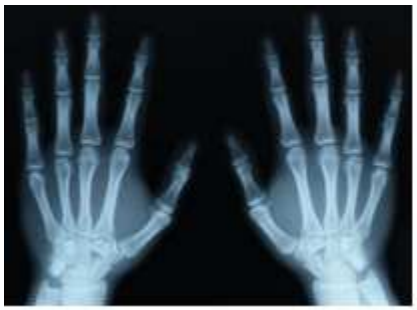

5. JFMDA supports and promotes GS1 Standards

✓**JFMDA continues promoting advanced IT infrastructure in Japan which is harmonized with GS1 Standards in intimate partnership with GS1 Japan.**

✓**JFMDA welcomes cooperation with all the participants of GS1 Healthcare Conference to promote patient safety, efficient supply chain and securing traceability.**

THANK YOU, GS1 FAMILY!!

医機連
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