Synex

Healthcare Market Access

Unique Device Identification (UDI):
What is happening in Korea?

May 11, 2017

Young Kim
Synex Consulting Ltd.

Synex
Healthcare Market Access

Objectives

- **The Ministry of Food & Drug Safety (MFDS) plans to introduce a UDI system to the Korean medical device regulation.**

- **This is to share information on the overall plan of MFDS and the current status of preparation.**

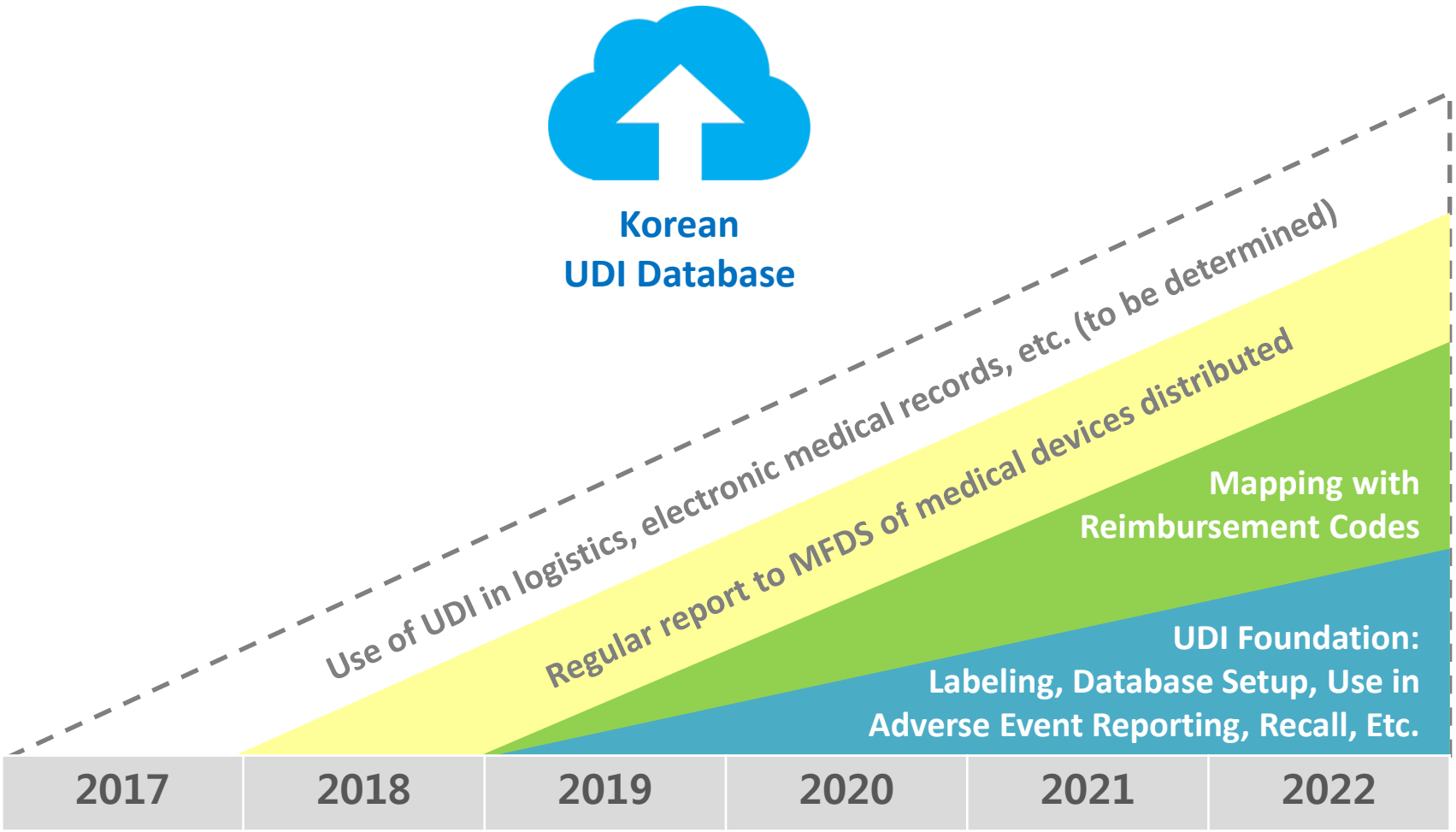
Why is Korea interested in UDI?

- **To improve patient safety**
  - The UDI is a useful tool to improve patient safety by enabling more accurate identification of medical devices especially in circumstances where public safety management is needed, such as, adverse event reporting, recall and by disseminating information for safe use of devices.

- **To level up international harmonization in medical device regulation**
  - One of the most important policy directions for MFDS in medical device regulation.

- **To improve accuracy in statistics on the medical device industry in Korea**
  - The UDI can be instrumental in collecting more accurate information on the medical device industry efficiently.
  - The MFDS has imbedded the requirement for medical device companies reporting information on their distribution to MFDS.

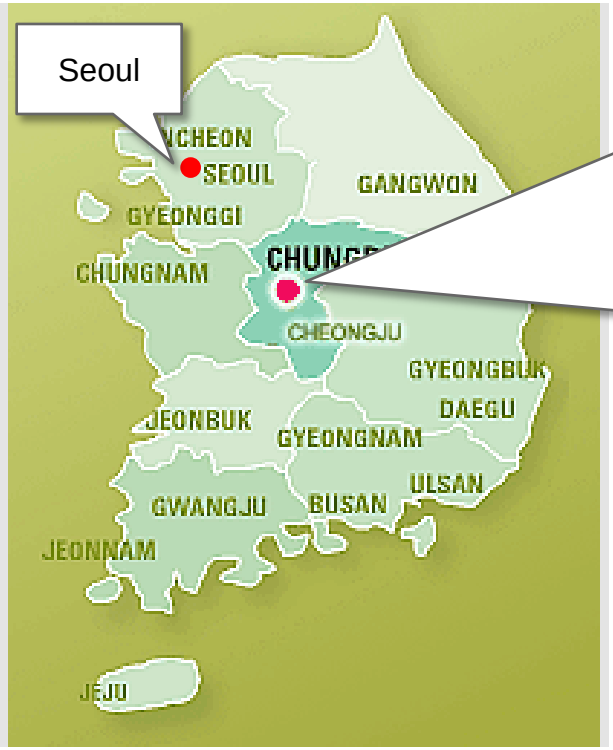
UDI in Korea: Scope of Potential Utilizations



The Lead Authority

Ministry of Food and Drug Safety(MFDS)

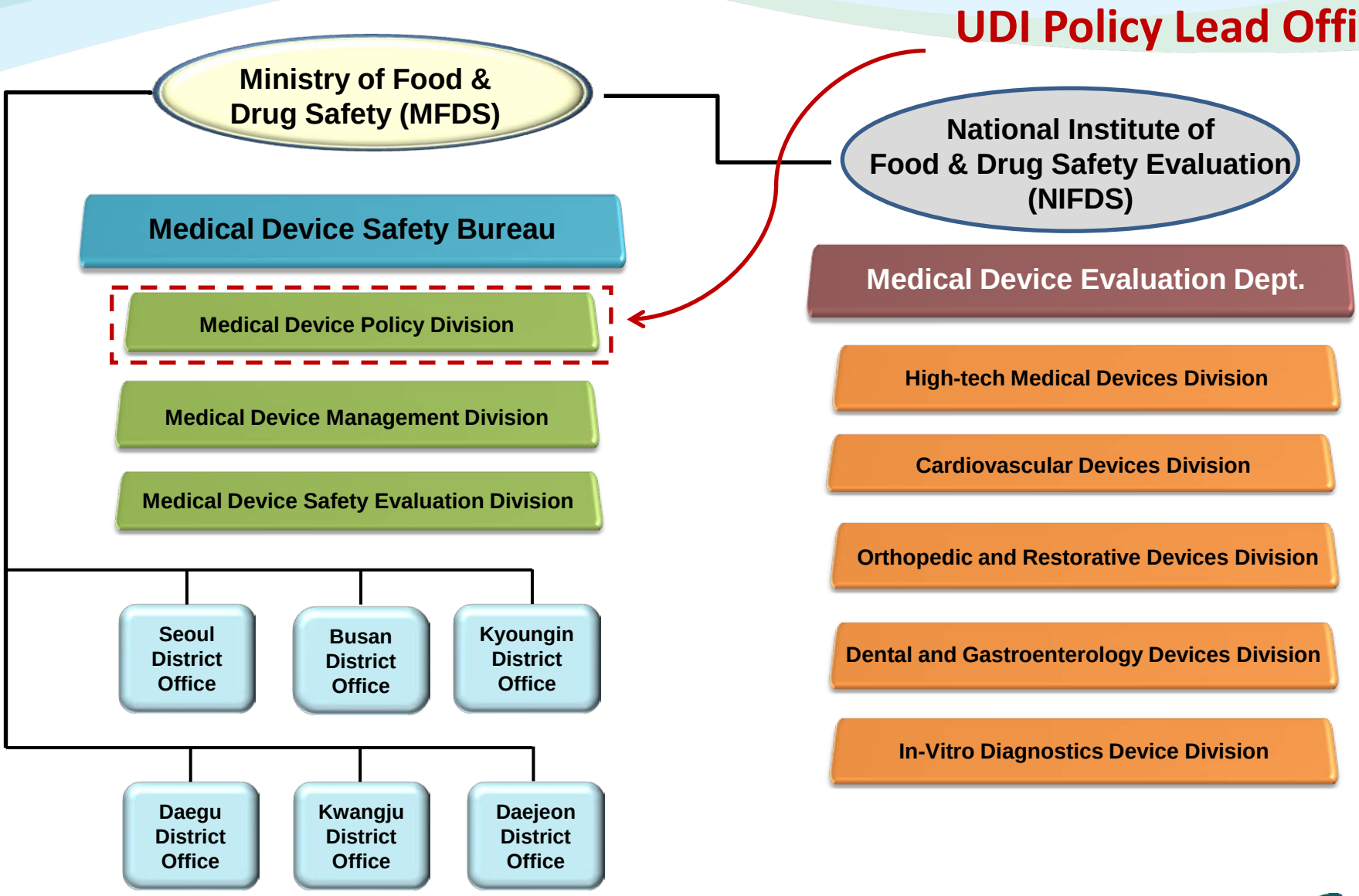
- ✓ MFDS has the exclusive authority for regulating medical devices.
- ✓ National Institute of Food & Drug Safety Evaluation (NIFDS) is the subordinate organization of MFDS to review Technical Documentation of medical devices.



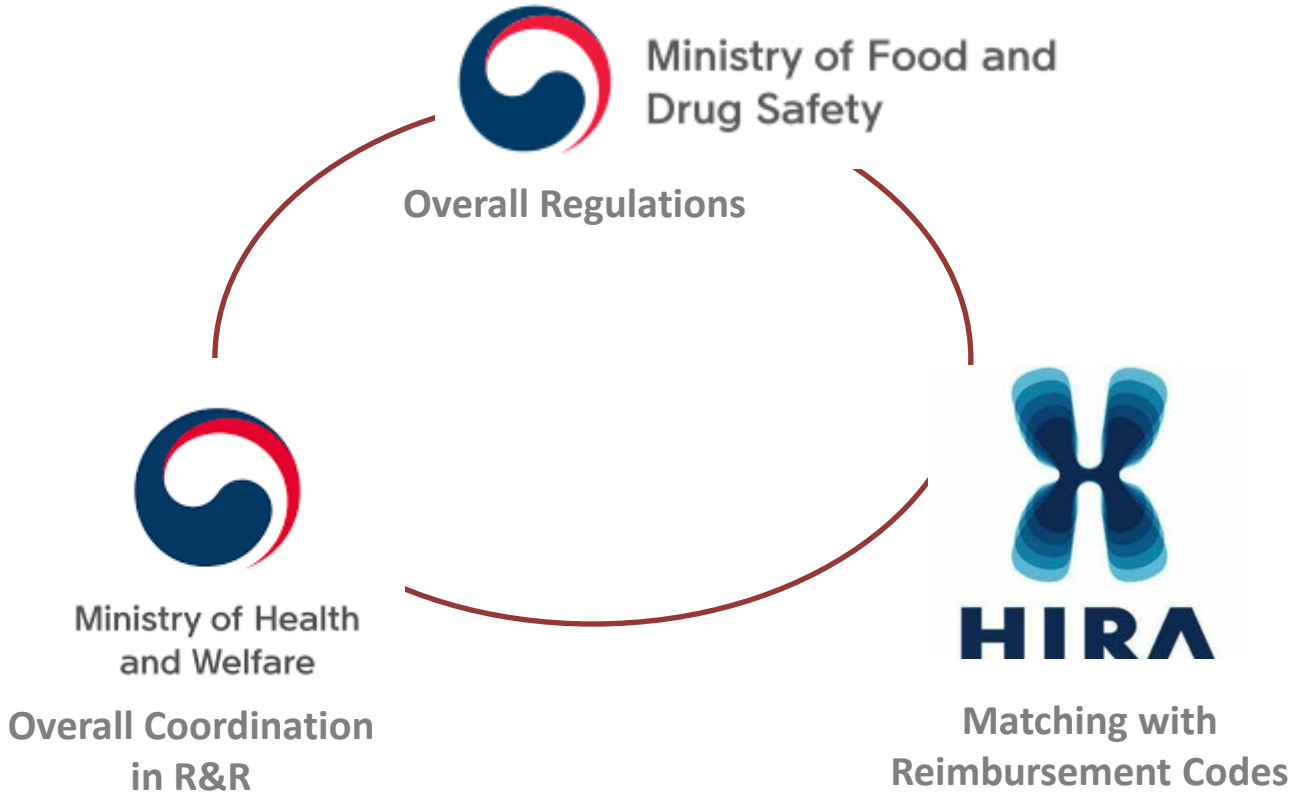
- ✓ The offices of MFDS and NIFDS are located in the city of Osong, Chungbuk, 120km south of Korea.

Synex Healthcare Market Access

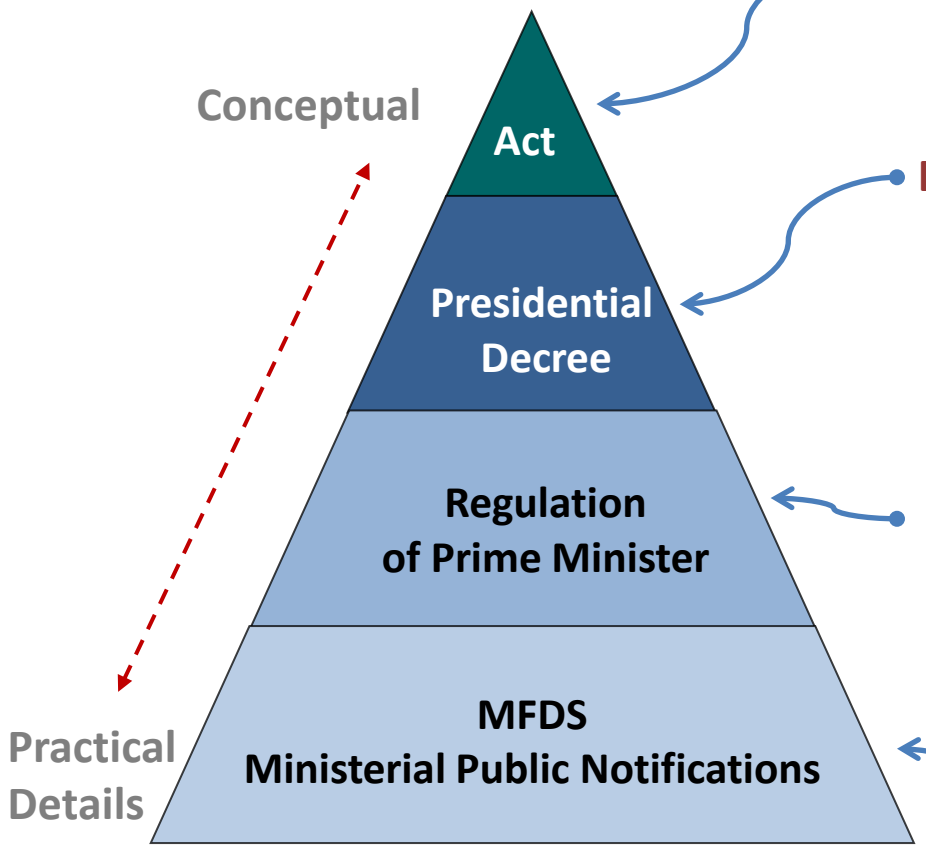
The Lead Office



The Co-Work Authorities



MFDS is working on necessary regulations…



Medical Device Act

– Revised on December 2, 2016 to lay down the legal ground of UDI

Enforcement Decree

– A draft revision published on February 7, 2017 to appoint a non-government organization to support MFDS for operation of the UDI database system

Enforcement Regulation

– MFDS is working on a revision to be published for comments during Q2 2017

MFDS has yet to work on many more details…

Terms Used in Korean Regulations

- **UDI: Standard Code**
- **UDI Database: Medical Device Consolidated Information System (MDCIS)**
  - **For convenience of this presentation, this system will be referred to as MDCIS hereinafter**

Major Changes in Medical Device Act

(Law No. 14330 revised on December 2, 2016)

Article 20 Subparagraph 8

- Require UDI labeled on medical devices

Article 31-2

- Require medical device manufacturers, importers, distributors and rental companies report to MFDS their sales records

Article 31-3

- Medical Device Consolidated Information System (MDICS) to be established by this law
- Require manufacturers and importers register information on UDI and medical devices with the MDCIS

Article 31-4

- Assign the task of operating the MDCIS to the MDCIS center to be newly established

- **UDI Implementation Date: The Prime Minister to determine an enforcement date within five years of the enforcement date of the revised Medical Device Act (Before December 2, 2021)**

Proposed Changes in Enforcement Decree

(MFDS Public Notice No. 2017-57, February 7, 2017;
to be finalized by June 2017)

Article 10-3

- **Proposed to designate the Medical Device Information and Technical Assistance Center (MDITAC) to the organization for the Medical Device Information Consolidation System (MDICS)**

- **Proposed the work scope of the MDICS as follows:**
  - **Collect, process, use and release the information on approved medical devices and their distribution**
  - **Operate the Medical Device Information Consolidation System (MDICS)**
  - **Administer the standard codes of medical devices (UDI)**
  - **Develop software programs for submitting and registering information on UDI and**
  - **Develop plans for standardization of information on medical devices**
  - **Research, educate and publicity on UDI**
  - **Other activities determined as necessary by Minister of Food & Drug Safety**

Medical Device Information and Technical Assistance Center (MDITAC)

- **A non-profit organization established in 2012 under Medical Device Act**
- **MFDS supervises the responsibilities and performances of MDITAC**
- **MFDS has assigned MDITAC to the following tasks:**
  - **Technical review and certification of class 2 devices**
  - **Administration of Class 1 device reports**
  - **Analysis of adverse event reports**
  - **Training programs on medical device regulations, quality system, regulatory affairs professionals, etc.**
  - **Translation of international standards**
  - **Consultations for medical device R&D**

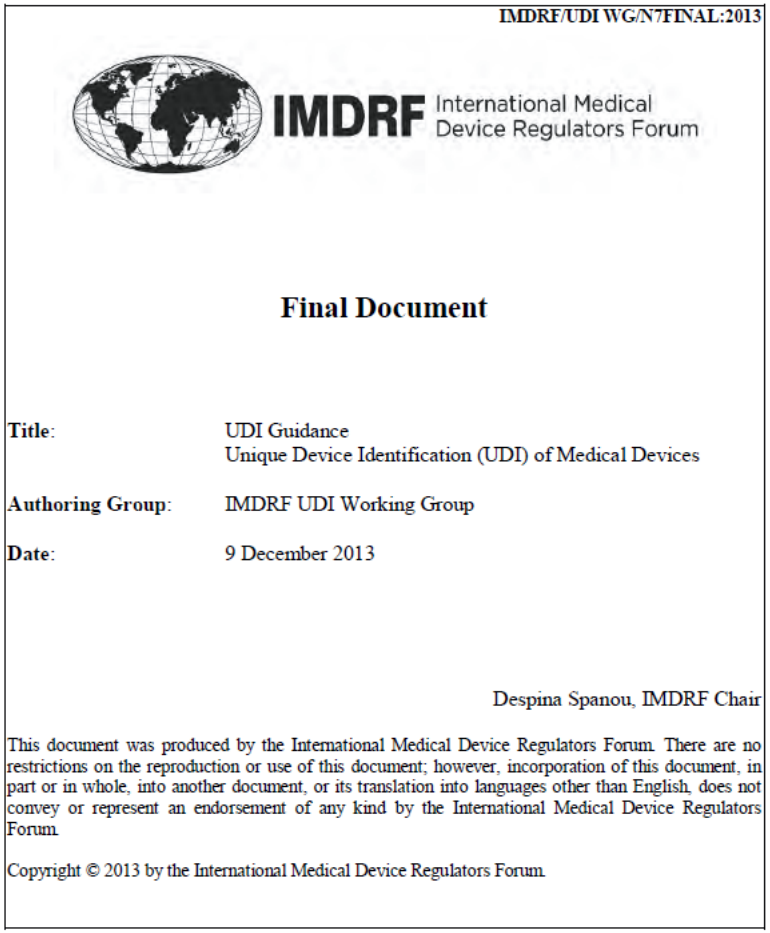
Proposed Changes in Enforcement Regulation

(To be finalized by July 2017)

- **To address the following scope of work and requirements:**
  - Detailed regulations for operating the MDICS
  - Scope of information to be registered with MDICS
  - Submission of information on distribution of medical devices through the MDICS

More regulations coming up…

- **MFDS is committed to harmonizing its UDI regulations internationally, e.g.,**
  - **IMDRF guidance**
  - **GS1 standards**



IMDRF/UDI 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

Phase-in Schedule 2019-2022 (draft)

UDI begins with high-risk devices

Descriptions		Class 4*	Class 3	Class 2	Class 1
Report to MFDS information on medical device sales	Manufacturer/ Importer	2018	2019	2020	2021
	Distributor/ Rental Company	2019	2020	2021	2022
Labeling UDI and Information Submission to the Korean UDI Database		2019	2020	2021	2022

*MFDS may designate at its discretion lower-class devices for earlier adoption of UDI.

UDI requires big changes for companies in Korea….

Pre-market

Design

Product Approval

Reimburse-ment Approval

Distribution

Manufacturing

Logistics

Electronic Medical Records

Post-market

Adverse event reporting

Tracking

Recall

Synex Healthcare Market Access

Thank you!

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Healthcare Market Access

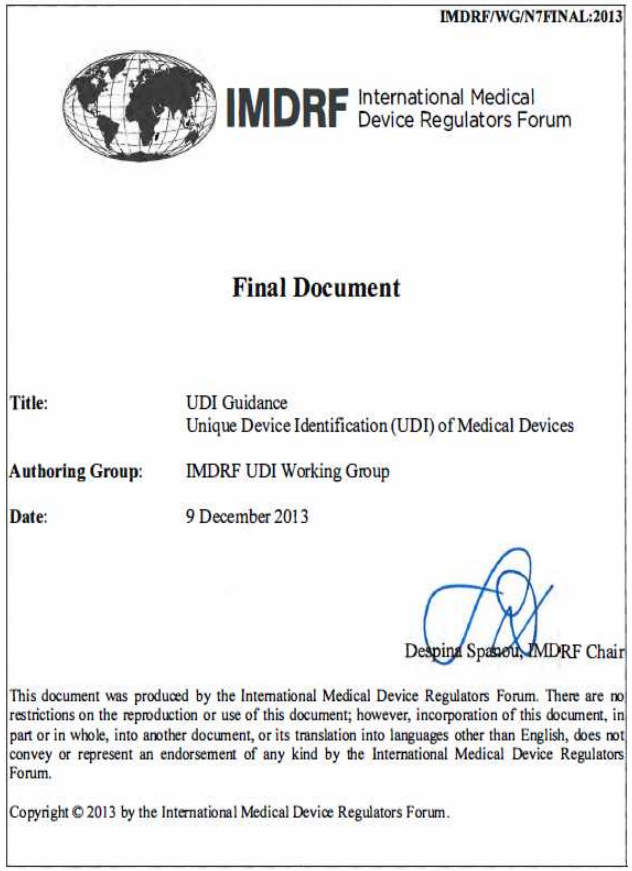
2nd Korea-Japan Joint Symposium on Medical Products

May 11, 2017

UDI and Traceability
From view of Medical Device Industries

The Japan Federation of Medical Devices Associations
Executive Director
EISHI HARASAWA (Mr.)

JFMDA
The Japan Federation of Medical Devices Associations



IMDRF/WG/N7FINAL:2013

IMDRF International Medical Device Regulators Forum

Final Document

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

Despina Spanou, IMDRF Chair

A globally harmonized and consistent approach to UDI is Expected to increase patient safety and help optimize patient care by facilitating the;

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,

Summary of UDI Implementation in Medical Devices Industry in Japan

1980s – Start using JAN (EAN-13)

1999 – Guideline ; Medical Device standardized code

2000 – Database for All Healthcare Products started by MEDIS-DC

2001 – MEDIS-DC ; Medical Information System Development Center

2006 – Revised Guideline (JFMDA) in 2006

2007 – MHLW issued “Guideline for Barcode Labeling of Medical Devices” in March 2008

2008 – 2009 – Published Practical Use Manual (JFMDA) in 2009

2010 – 2016 – Revised Manual (JFMDA) in 2016

Started “UDI and Traceability Promotion Conference” (JFMDA)

2017

Barcode Labeling and Register in the Database of Medical Devices in 2016

◆ Barcode Labeling

Primary Package	***86.4%***
Sales Package (Inner and outer)	***94.5%***

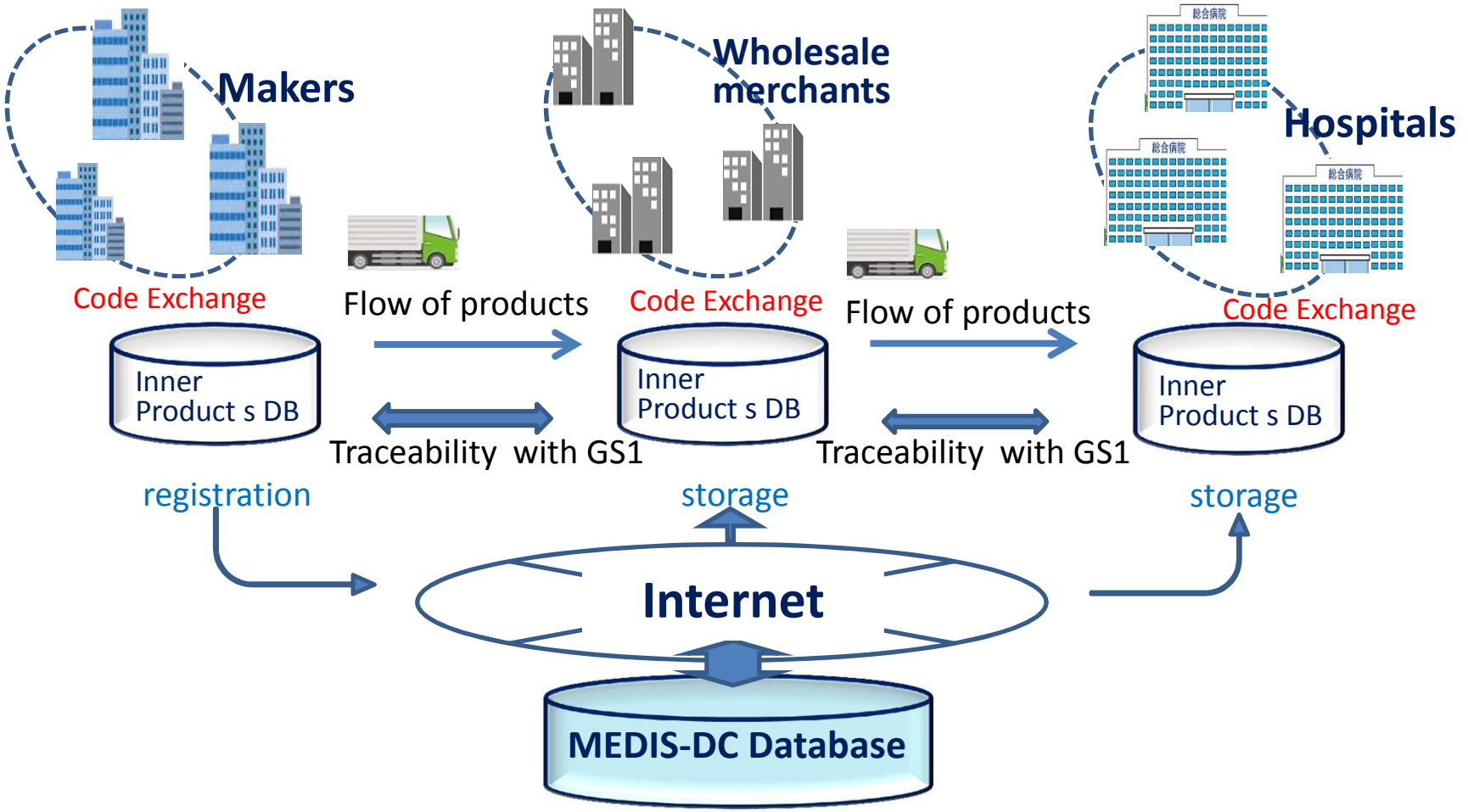
◆ Register in MEDIS database

Medical Devices	**77.2%**

MEDIS-DC ; Medical Information System Development Center

Current Situation in Japan

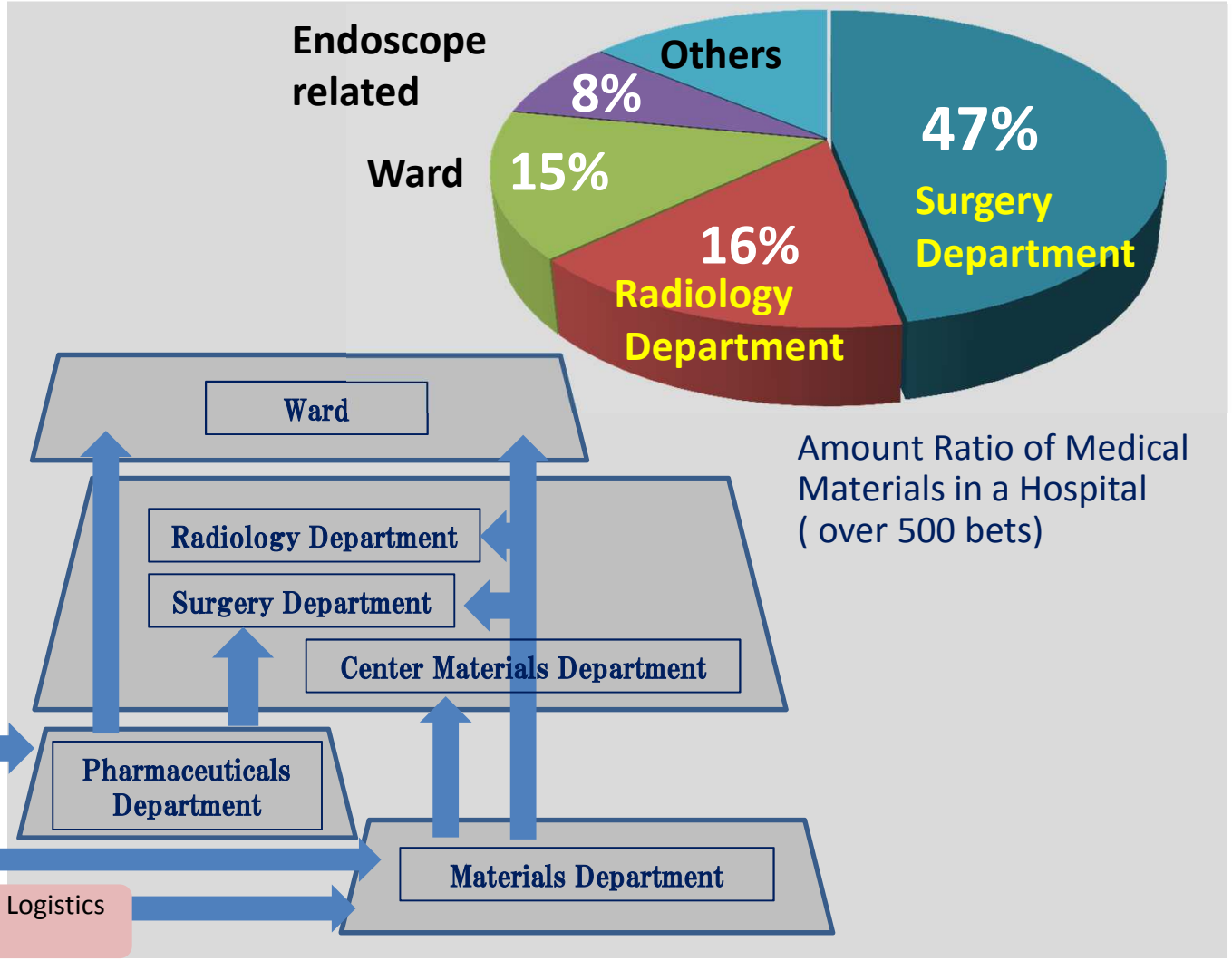
(hospitals, wholesale merchants, makers)



MEDIS-DC ; Medical Information System Development Center

Current Situation in Japan

(Amount Ratio of Medical Materials in a Hospital)

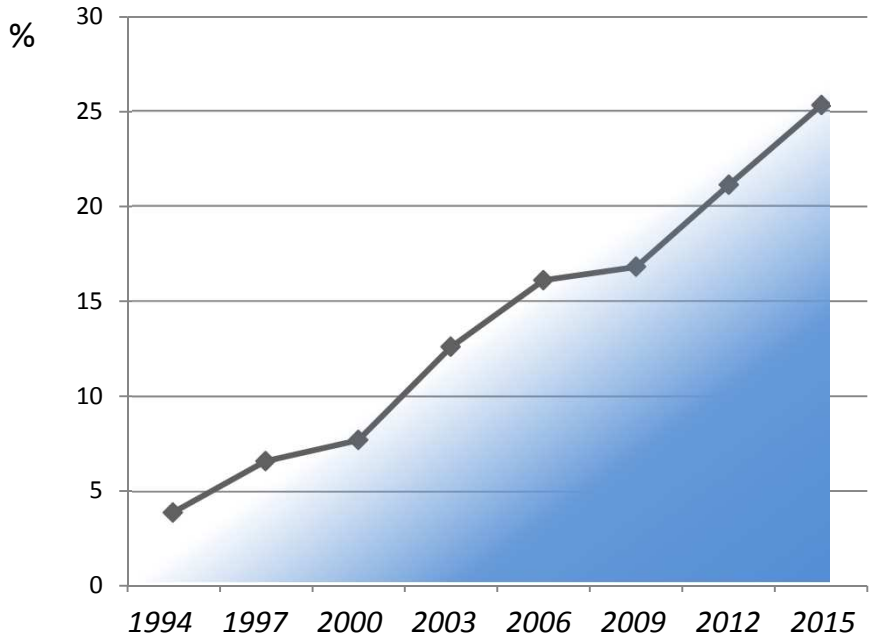


Amount Ratio of Medical Materials in a Hospital (over 500 bets)

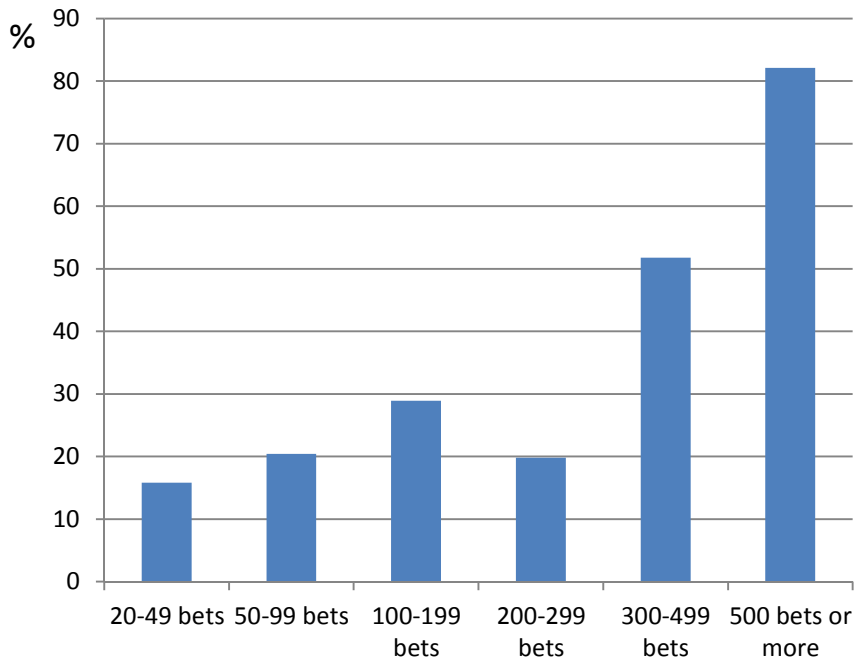
Current Situation in Japan

(Outsourcing of Medical Logistics Service in Hospital)

Growth Rate



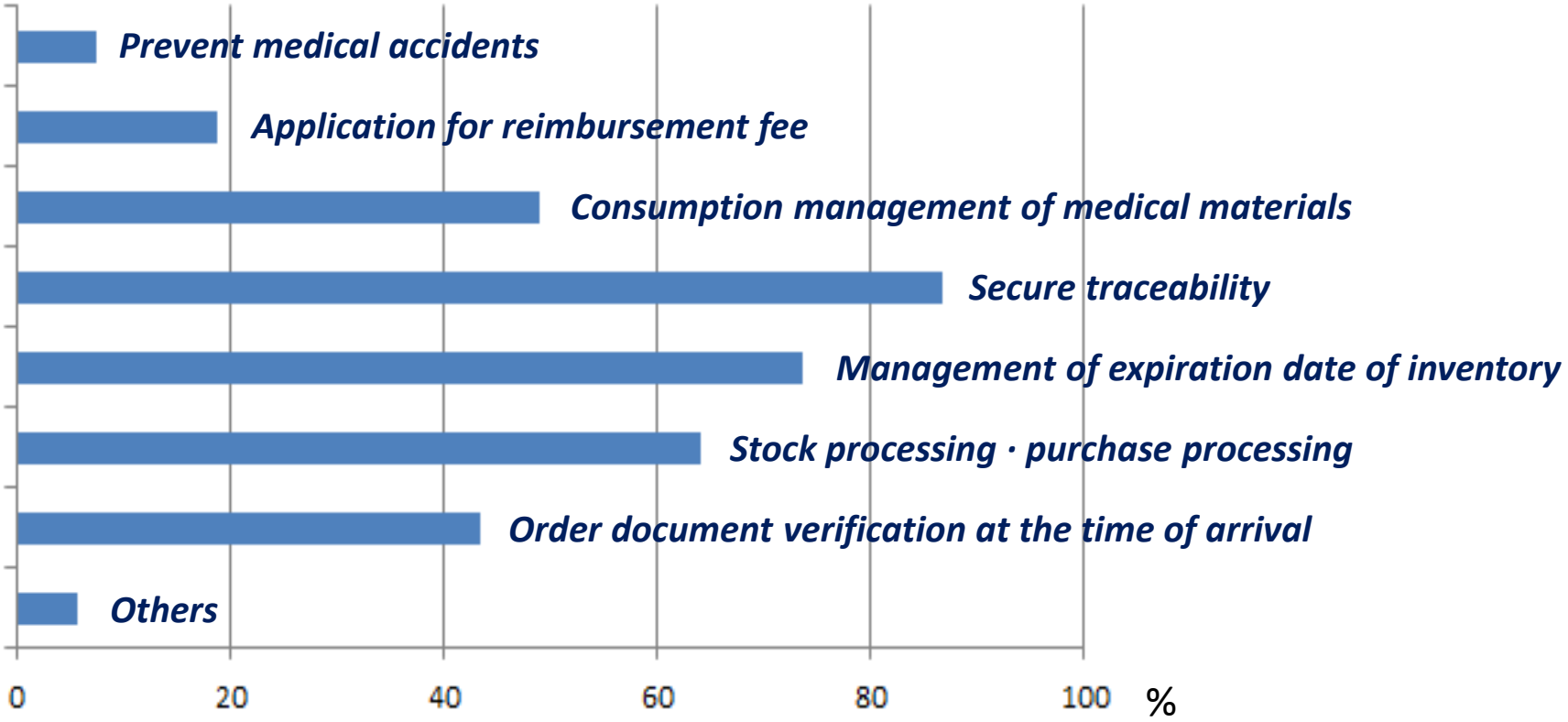
Penetration Rate



Source ; Medical related service actual condition survey report 2015 by Japan Health Enterprise Foundation

Current Situation in Japan
(Intended Use of UDI)

JAHID conducted a questionnaire survey for 270 general hospitals (over 300 bets) in 2012



Current Situation in Japan

The UDI have been widely used in large hospitals, not in the small and medium-sized hospitals in Japan.

In Japan, many local codes including codes used in hospitals are used, and many hospitals outsource their medical material management. Although DI of the standard code（GS1）linked with the local code is used, PI（ lot number or serial number）is still not used much.

Now, the Key is to promote the benefit of GS1 product identification & barcodes and encourage healthcare providers and hospitals to use them.

Next Step; As “Team Japan”

In December 2016, *the Medical Product Identification and Traceability Promotion Conference* consisting of all stakeholders of industry, academia, medical care and public administration started by the call of JFMDA.

We need to make efforts to improve medical quality, ensure patient safety, and improve medical efficiency.

It is our belief that now is the time for Japanese healthcare systems to take action as TEAM JAPAN.

2nd Korea-Japan Joint Symposium on Medical Products

Regulatory requirements for medical device software in Korea

11th May 2017

Prepared by MinYong Choi

Head of Healthcare, BSI Group Korea

Agenda

- Regulatory Authority
- Definition of Medical Device
- Regulatory Scope for Medical Device Software
- Medical Device Regulations Framework
- MFDS Notifications for Medical Device Software
- MFDS Guidelines for Medical Device Software

Introduction of MinYong Choi

Head of Healthcare, BSI Group Korea

- T: +82 2 6271 4020, F: +82 2 777 4123
- E: minyong.choi@bsigroup.com

Background:

- 2016~Present BSI Group Korea, Head of Healthcare
- 2016~Present IEC TC 62 SCA Committee Member
- 2016~Present IEC SyC AAL Committee Member
- 2012~2016 UL Korea, Medical Solutions, Business Development Manager
- 2005~2011 KFDA (MFDS), Medical Device Evaluation Department, Technical Reviewer

Regulatory Authority

Korea MFDS (Ministry of Food & Drug Safety), http://www.mfds.go.kr

Minister

식품의약품안전처

Definition of Medical Device

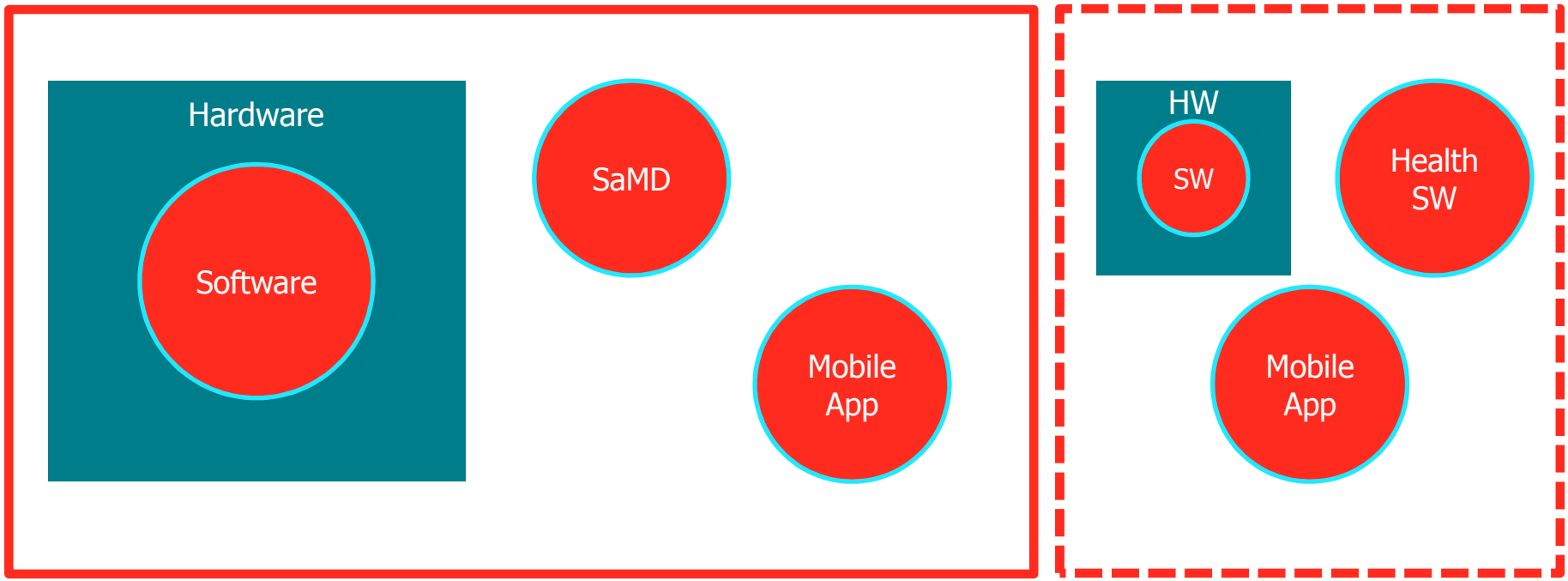
Medical Device Act, Article 2 (Definition)

"의료기기"란 사람이나 동물에게 단독 또는 조합하여 사용되는 기구·기계·장치·재료 또는 이와 유사한 제품으로서 다음 각 호의 어느 하나에 해당하는 제품을 말한다.

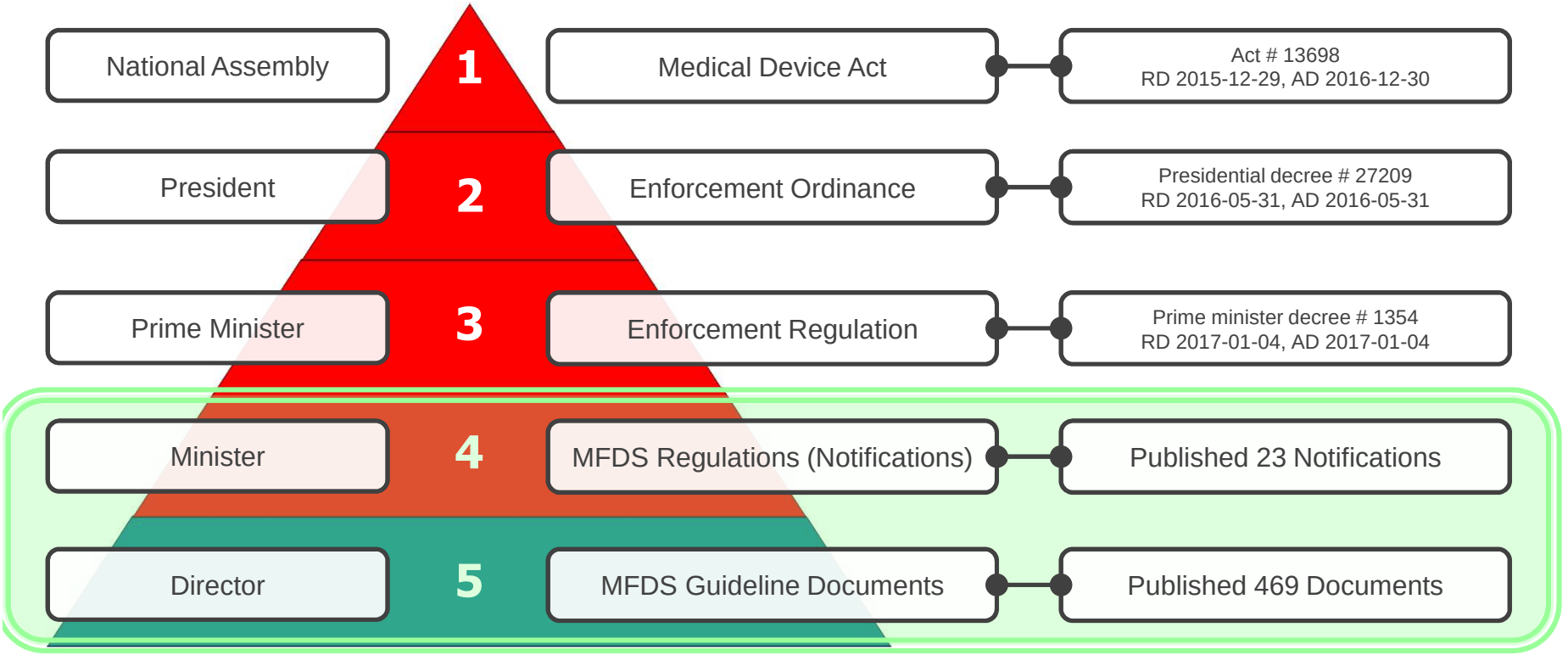
The term "medical device" in this Act means an **instrument, machine, apparatus, material, or any other similar product** specified in the following subparagraphs as one used, alone or in combination, **for human beings or animals**:

Source: http://elaw.klri.re.kr/kor_service/lawView.do?hseq=37286&lang=ENG

Regulatory Scope for Medical Device Software



Medical Device Regulations Framework



Mandatory

Not Mandatory

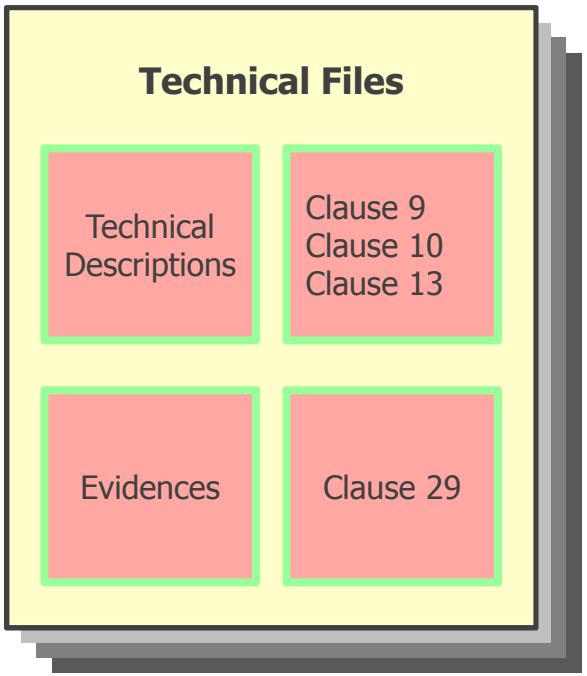
MFDS Notifications for Medical Device Software

MFDS Notifications for Medical Device Software

Notification ID	Title of Notification	Published/ Revised Date	Description
2016-132	의료기기 허가 신고 심사 등에 관한 규정	2016-12-07	Medical Device Registrations, Technical Documentations
2016-156	의료기기 제조 및 품질관리 기준	2016-12-30	GMP, Quality Management System
2017-6	의료기기 품목 및 품목별 등급에 관한 규정	2017-01-24	Medical Device Classification
2016-2	의료기기 부작용 등 안전성 정보 관리에 관한 규정	2016-01-14	Reporting for Adverse Event or Safety Information
2015-115	의료기기의 전기 기계적 안전에 관한 공통기준규격 [별표 1]	2015-12-31	IEC 60601-1:2012, ED 3.1

MFDS Notification #2016-132

- Clause 9 (Shape & Structure) 모양 및 구조
  - Software Structure (Architecture) and Functions
- Clause 10 (Raw Materials) 원재료
  - Software Name, Version and Operating Environment
- Clause 13 (Instructions for Use) 사용방법
  - Software UI Pictures, Description of Functions and Use Instructions
- Clause 29 (Attached Documents Requirements) 첨부자료의 요건
  - Software Validation Report using Report Form in Appendix 13



MFDS Notification #2016-132

- Clause 55 (Exemptions of Medical Device Selling Business License) 의료기기 판매업 신고가 면제되는 의료기기
  - Mobile Medical Apps using self-diagnostics
  - Devices (Mobile phone, Tablet PC, PC, …) including Mobile Medical Apps using self-diagnostics

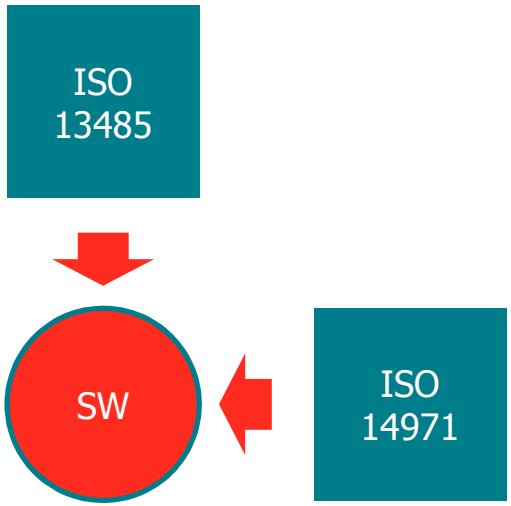
- Clause 59 (Permission of Performance Upgrade/Improvement) 성능개선 허용 대상
  - Software changes or upgrades can be allowed.
  - The medical device related to the software have to be approved the changes or upgrades through the medical device change registration process before the software changes or upgrades.

MFDS Notification #2016-132

- Appendix 3 Minor Changes for Software (Self Control Cases)
  - 36. Bug fix on mobile medical apps
  - 37. Version changes by bug fix on medical device software without any functions changes and safety/performance effects
  - 38. Version changes by modification of graphic user interfaces (color, menu position, …) without any functions changes and safety/performance effects
  - 52. Modification of graphic user interfaces (color, menu position, …) without any functions changes and safety/performance effects
  - 103. Version changes by additions of multi-language data without any functions changes and safety/performance effects

MFDS Notification #2016-132

- Appendix 10 STED: Summary Technical Documentation
  - 2.7.7 Summary of Software Verification and Validation



Process	Activities
Software Design & Development	Software Planning
	Software Requirement Specification
	Software Architecture Design
	Software Detail Design
	Software Testing/Verification and Validation
	Software Release
Software Maintenance	Change, Problem Resolution
	Documentation
	Configuration Management

MFDS Notification #2016-132

- Appendix 13 Software Validation Report
  - Report Form #13

Software Design & Development
Software Planning
Software Requirement Specification
Software Architecture Design
Software Detail Design
Software Testing/Verification and Validation
Software Release

Medical Device Software Validation Report			
Device Classification		Software Name & Version	
Software Type	[ ] Deployed on Device [ ] SaMD		
Software Functional Characteristics	[ ] Control [ ] Measurement [ ] Analysis [ ] Diagnosis [ ] Data Processing [ ] Data Transmission [ ] Data Reception [ ] Display [ ] Others		
Software Safety Classification	[ ] Class A [ ] Class B [ ] Class C		
Intended Purpose of Software		Software Operation Environment	
Software Design & Development			
Software Maintenance & Problem Resolution			
Software Risk Management			
Software Configuration Management			

MFDS Notification #2016-156

Criteria for Medical Device Manufacturing & Quality Management

- Based on ISO 13485:2003
  - 6.3 Infrastructure
  - 7.5.2 Validation of processes for production and service provision
  - 7.6 Control of monitoring and measuring device

MFDS Notification #2017-6

Medical Device Classification

- This notification classify specific medical device softwares as medical devices

A26430.03 의료영상전송장치소프트웨어 **[2]**
Picture archiving and communication system, image processing, software

의료용 영상을 저장, 확대, 축소, 조회와 함께 분석, 전송 처리하는 장치 및 출력하는 장치에 사용되는 소프트웨어
A software which is intended to save, expand, reduce, analyze, transmit and print medical images

MFDS Notification #2016-2

Reporting for Adverse Event or Safety Information

- Medical Device Problem Codes

#	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
1	2914 기기의 작동 문제(Device Operational Issue) 기기 작동과 관련된 기준에서의 편향과 관련된 문제 (예: 배치, 연결, 전기, 컴퓨터 소프트웨어, 주입/흐름, 출력, 보호장구, 부적합 문제); Issue associated with any deviations from specifications relating to device operations (e.g. deployment, connection, electrical, computer software, infusion/flow, output, protective measure, and incompatibility issues)					
19		1112 컴퓨터 소프트웨어 문제(Computer Software Issue) 기기 성능 또는 다른 기기와의 통신에 영향을 미치는 문서화된 프로그램, 코드 및/또는 소프트웨어 시스템과 관련된 문제; Issue associated with written programs, codes, and/or software system that affects device performance or communication with another device.				
21			2880 응용프로그램 문제(Application Program Issue) 의도된 용도 내에서 기능을 충족시키기 위한 소프트웨어 또는 응용프로그램에 대한 요구사항과 관련된 문제; Issue associated with the requirement for software to fulfill its function within an intended use or application.			
25				3013 소프트웨어 설치 문제(Problem with Software Installation) 기기의 완전한 기능수행을 가능하게 하는 방법으로 기기 소프트웨어를 설치하는 것과 관련된 문제. 설치 소스는 제조업체 또는 사용자가 될 수 있다; Issue associated with installing the device software in a manner that allows full functioning of the device. Source of installation could be manufacturer or user.		

MFDS Notification #2016-2

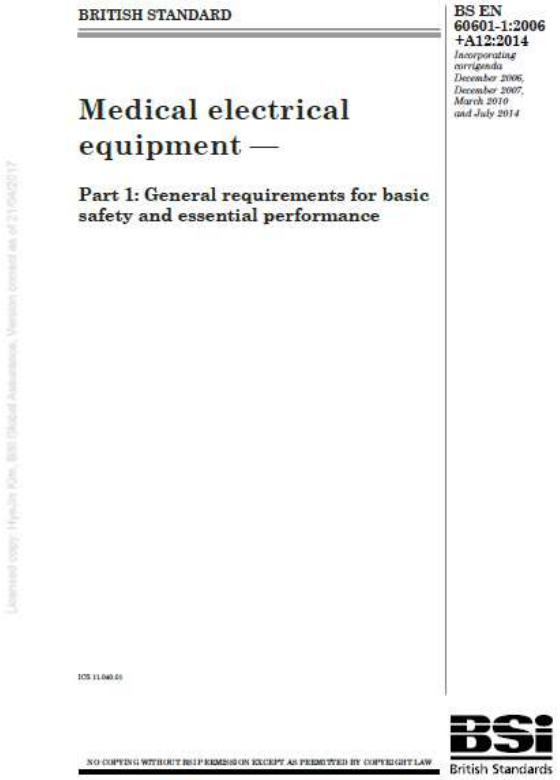
#	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
26				3014 프로그래밍 문제(Programming Issue) 기기의 기능 수행을 위한 기재된 요구 또는 목적을 충족시키기 위한 서면 프로그램 코드 또는 응용프로그램 소프트웨어와 관련된 문제. 여기에는 운영 체제와 관련된 문제는 포함되지 않는다; Issue associated with the written program code or application software used to satisfy a stated need or objective for functioning of the device. These do not include issues associated with the operating system.		
27					1495 부정확한 소프트웨어 프로그래밍 계산(Incorrect Software Programming Calculations)	
28						1189 소프트웨어 문제로 인한 용량 계산 오류(Dose Calculation Error due to Software Problem)
…						

MFDS Notification #2015-115

MFDS Standard for Electrical & Mechanical Safety

- Based on IEC 60601-1:2012, ED 3.1
  - Clause 14 PEMS (PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM)

Device Class	Day of Application
Class 4	2015-01-01
Class 3	2015-07-01
Class 2	2016-01-01
Class 1	2016-07-01


BRITISH STANDARD

BS EN 60601-1:2006 +A12:2014

Incorporating corrigenda December 2006, December 2007, March 2010 and July 2014

Medical electrical equipment —

Part 1: General requirements for basic safety and essential performance

BSI British Standards

MFDS Guidelines for Medical Device Software

MFDS Guidelines for Medical Device Software

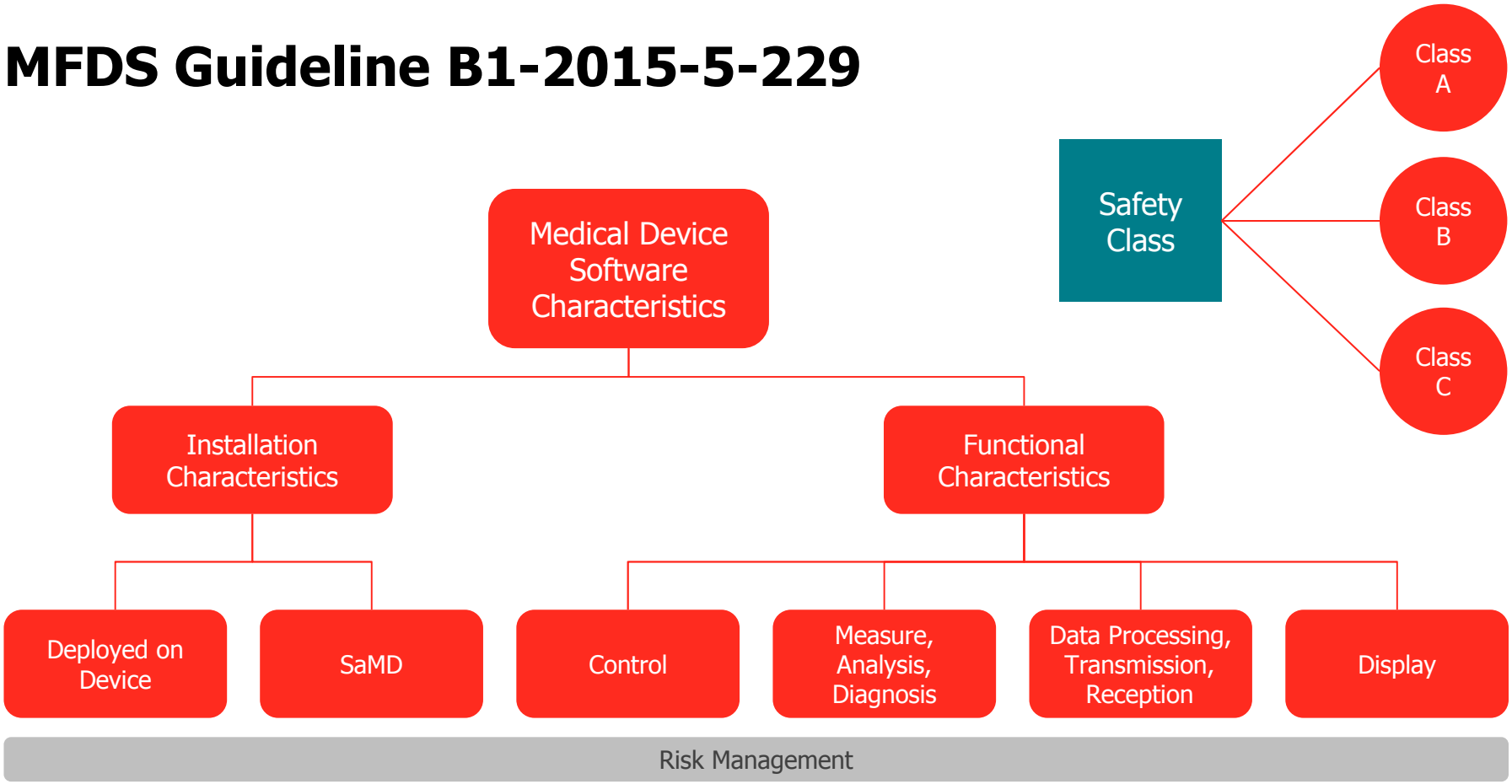
Guideline ID	Title of Guideline	Published/ Revised Date	Description
B1-2015-5-229	의료기기 소프트웨어 허가심사 가이드라인	2017-07-31	Software Requirements for Medical Device Registration
A0-2015-5-006	의료기기와 개인용 건강관리(웰니스) 제품 판단기준	2015-07-10	Wellness Devices
B1-2015-5-105	휴대형의료영상전송장치 소프트웨어 허가심사 가이드라인	2015-02-27	Requirements for Mobile PACS Registration
B1-2015-5-107	의료영상전송장치 소프트웨어 기술문서 작성을 위한 가이드라인	2015-02-27	Requirements for PACS Registration
A0-2013-5-006	모바일 의료용 앱 안전관리 지침	2013-12-31	Mobile Medical Apps
B2-2007-5-004	의료기기 소프트웨어 밸리데이션 가이드라인	2007-01-01	Medical Device Software Validation

MFDS Guideline B1-2015-5-229

Software Requirements for Medical Device Registration

- Scope of Application
- Terms & Definitions
- Software Safety Class
- Technical Documentation Guide
- Software V&V Report
- Technical Documentation Examples

MFDS Guideline B1-2015-5-229



MFDS Guideline A0-2015-5-006

Wellness Devices

- Criteria for determining Wellness Devices
- Criteria for Wellness Devices regulated as Medical Devices
  - Third level 14 black non bold, teal bullet
  - Scope of application
  - Definition of wellness device
  - Identification criteria for wellness device
  - Examples for wellness device
  - Process for official questioning to MFDS
  - Recommendations for safer use of wellness device

MFDS Guideline A0-2015-5-006

Definitions

Medical Device

A device like any instrument, machine, contrivance, or material which is intended to be used for human beings or animals by itself or combination with others

- For the purpose of diagnosis, therapy, alleviation, treatment, or prevention of the illness
- For the purpose of diagnosis, therapy, alleviation, or compensation of the injury or disability
- For the purpose of test, replacement, or modification of the structure or functions of the body
- For the purpose of control of the conception

Wellness Device

A device like any instrument, machine, contrivance, material, software, or application which is intended to be used for human beings by itself or combination with others

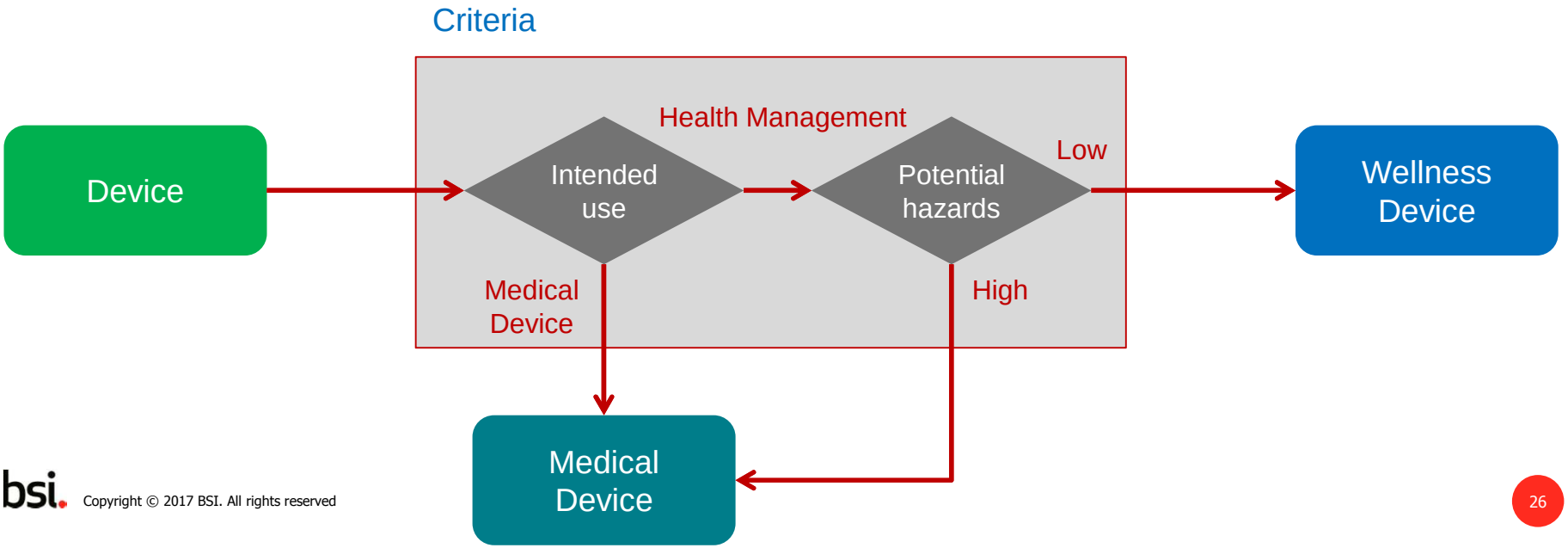
- For the purpose of maintaining or improving of the general healthy condition or activity
- For the purpose of inducing of the healthy life style or habit
- For the purpose of supporting self management for **chronic disease**

Chronic disease: Cardiac disorder, Hypertension, Hypotension, Diabetes, …

MFDS Guideline A0-2015-5-006

General principle for determination criteria

- The wellness device shall be identified by the intended use of the device and the potential hazards which are included in the device



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High level potential hazards

- Leading to the biocompatibility issue
- Being used invasively
- Leading to the injury or illness during the fault condition
- Monitoring the emergency situation
- Controlling or modifying the device characteristic or function

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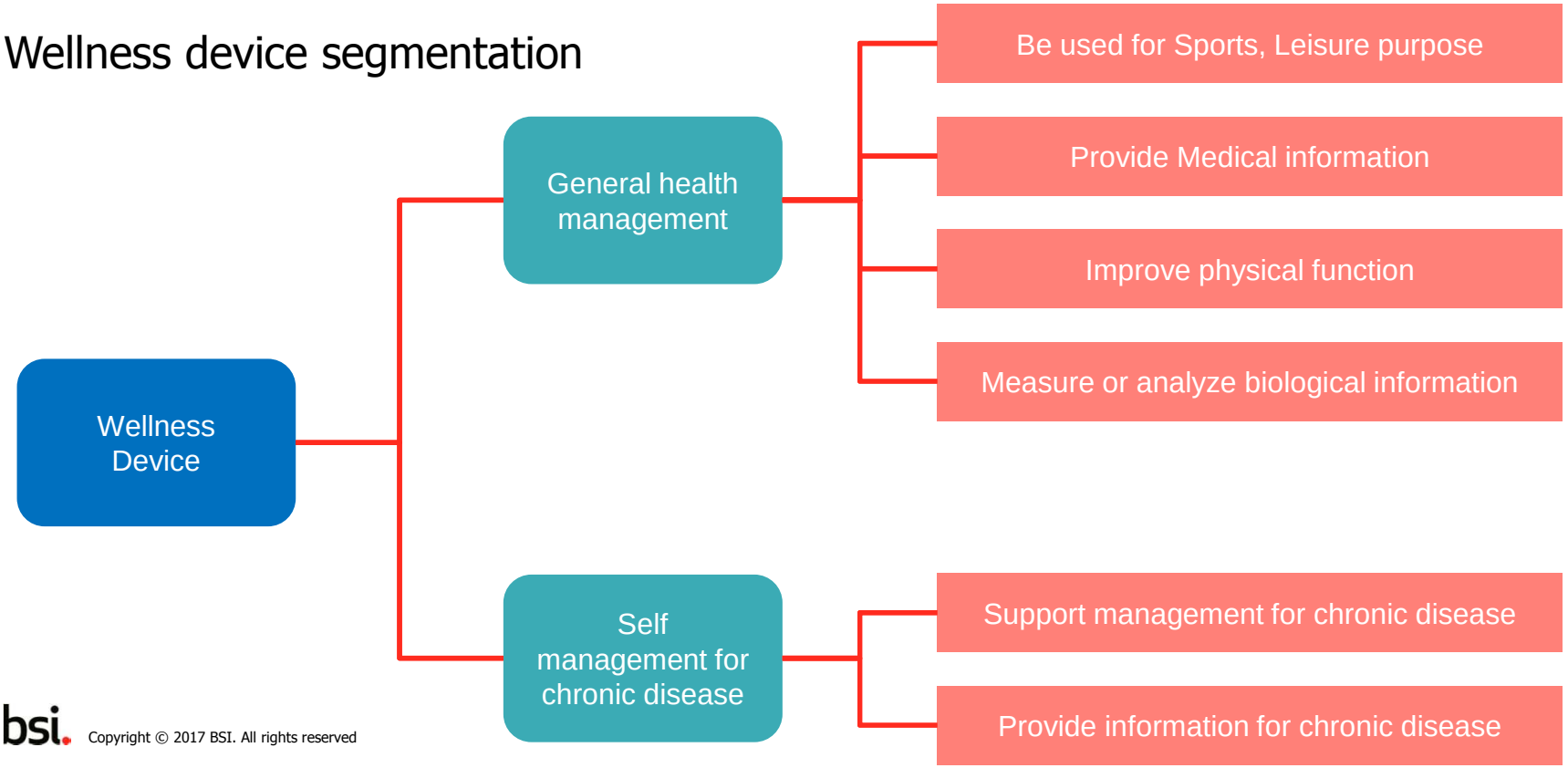
Wellness device segmentation



MFDS Guideline A0-2015-5-006

MFDS Recommendations for Wellness Device Manufacturers

- MFDS recommends that the wellness device manufacturer should establish the quality management system for ensuring the device quality and safety.
- The quality management system should include the procedures related to the post-market surveillance and vigilance system.
- The below recommended caution sentence should be attached on the wellness device. (or should be displayed in the wellness device.)

This device is not a medical device.
This device can't be used for the diagnosis of illness.
You shall receive a medical treatment from the medical specialist to get the diagnosis of your illness correctly.

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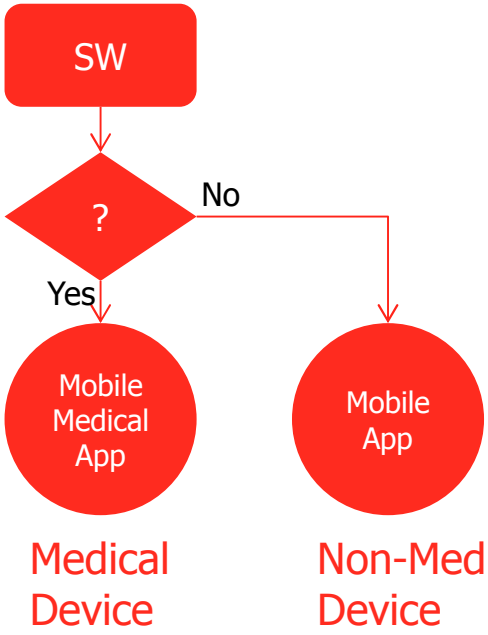
Mobile Medical Apps

- Criteria for determining Mobile Medical App

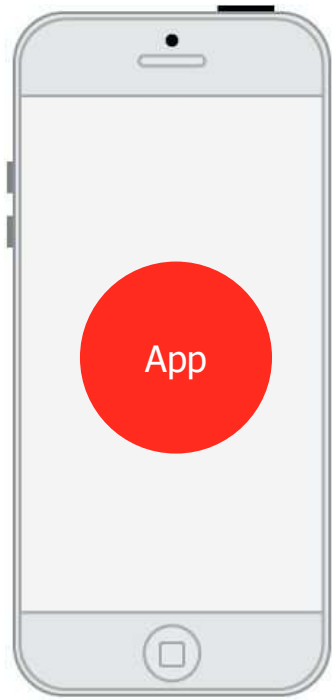


모바일 의료용 앱 안전관리 지침

2013. 12. 26.

식품의약품안전처
MINISTRY OF FOOD AND DRUG SAFETY

MFDS Guideline A0-2013-5-006



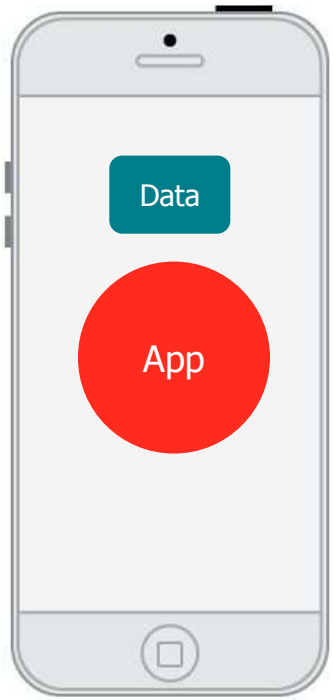
Smart Phone

Control

Medical Device

MFDS Guideline A0-2013-5-006

Display
Save
Analysis

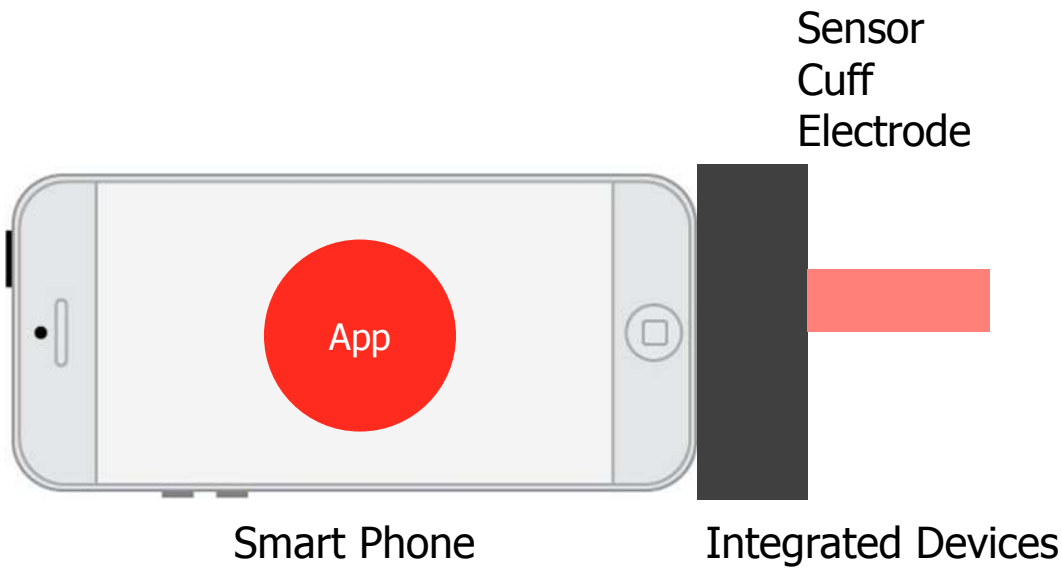


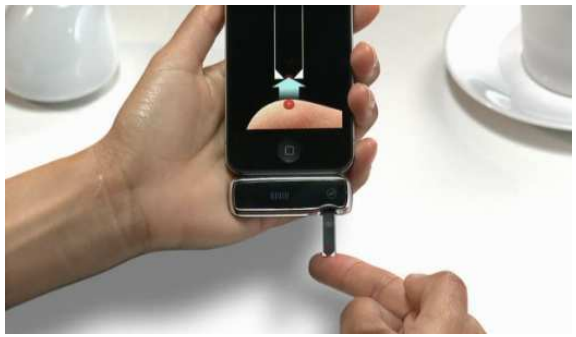
Smart Phone

Data Transmission

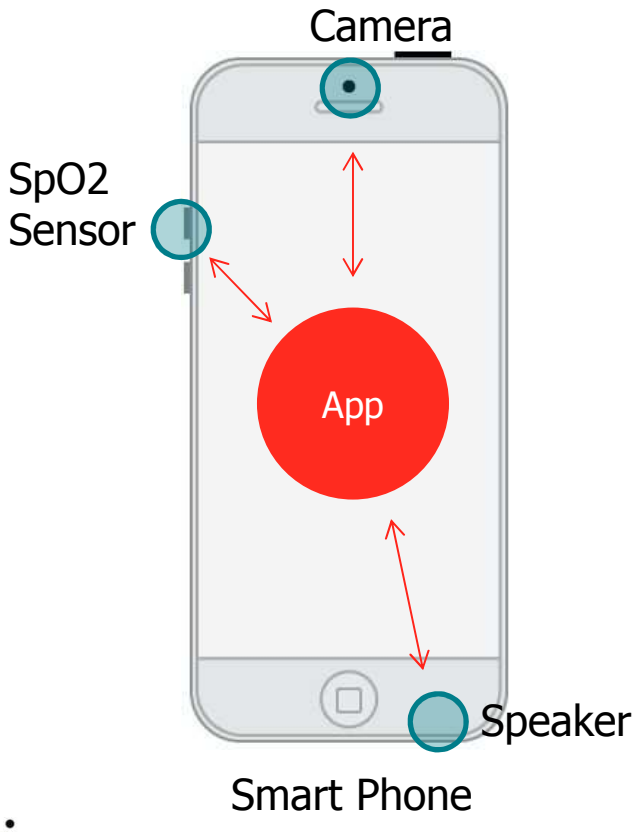
Medical Device

MFDS Guideline A0-2013-5-006





MFDS Guideline A0-2013-5-006



MFDS Guideline A0-2013-5-006

Medical Device

Data

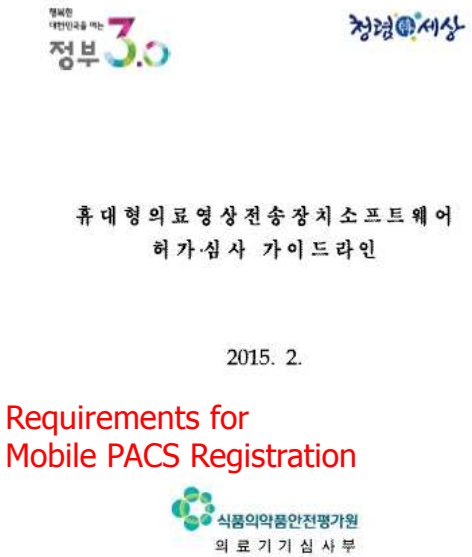
Data Input

App

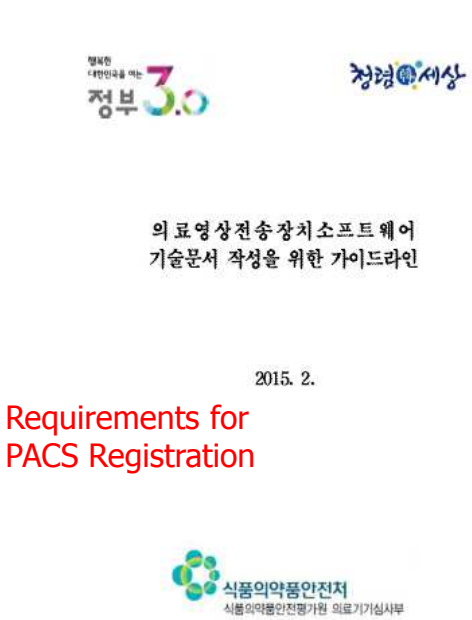
Diagnosis

Determine Therapeutic Method

Smart Phone



MFDS Guideline B1-2015-5-105



MFDS Guideline B1-2015-5-107

MFDS Guideline B2-2007-5-004

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Thank you.

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Medical Software Regulation in Japan

Keiichiro Ozawa

FUJIFILM Corporation

Agenda

0. Introduction
1. Qualification and Classification
2. Low Risk Software
3. Creating Certification Standards
4. Pre-market Application and Validation
5. Cybersecurity

Introduction of Keiichiro Ozawa

FUJIFILM
Value from Innovation

Name: *Keiichiro Ozawa*

Company Name: *FUJIFILM Corporation*

Business Title: *Regulatory Specialist*

Biography:

Jeju

- ***Member of JFMDA Medical Device Software Working Group (The Japan Federation of Medical Devices Associations)***
- ***Member of IMDRF SaMD Working Group***
- ***Chair of DITTA Medical Software WG***

  (Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association)
- ***IEC Expert of TC62/SC62A/JWG7***
- ***Member of AHWP WG1***

1-1. Qualification of Medical Device Software

Revision of Pharmaceutical Affairs Law

- Japanese Pharmaceutical Affairs Law has been revised as "PMD Act" and it has been in effect since Nov. 25, 2014.

- One of the significant points of the revision was the implementation of revised GHTF Essential Principles (2012) which led to the ***introduction of standalone medical device software*** into the Japanese regulatory system.

1-1. Qualification of Medical Device Software

Software qualified as a medical device

Notification on the basic concept of the qualification of medical device software, MHLW, Nov. 14, 2014

● The intended use of the medical device software is based on the definition of the medical device, … installed in general-purpose PC or handheld terminals".

1) Software which **creates indices, images, charts for diagnosis or treatment** by means of processing data from medical devices

2) Software which supports the decision of **treatment plan or treatment method** (including simulation software)

1-1. Qualification of Medical Device Software

Software qualified as a non-medical device

1) Software which transfers, stores and displays data from medial devices used as medical records
2) Software which processes or computerizes data except image data for the purpose other than diagnosis
3) Software for education
4) Software for patient explanation
5) Software for maintenance
6) Software for hospital business support
7) Software for health management
8) Software equivalent to General Medical Device (Class I equivalent)

1-2. Classification of Medical Device Software

PMD Act employs basic concept of GHTF rule for medical device classification.
→ Principles of Medical Devices Classification, GHTF, Nov. 2, 2012

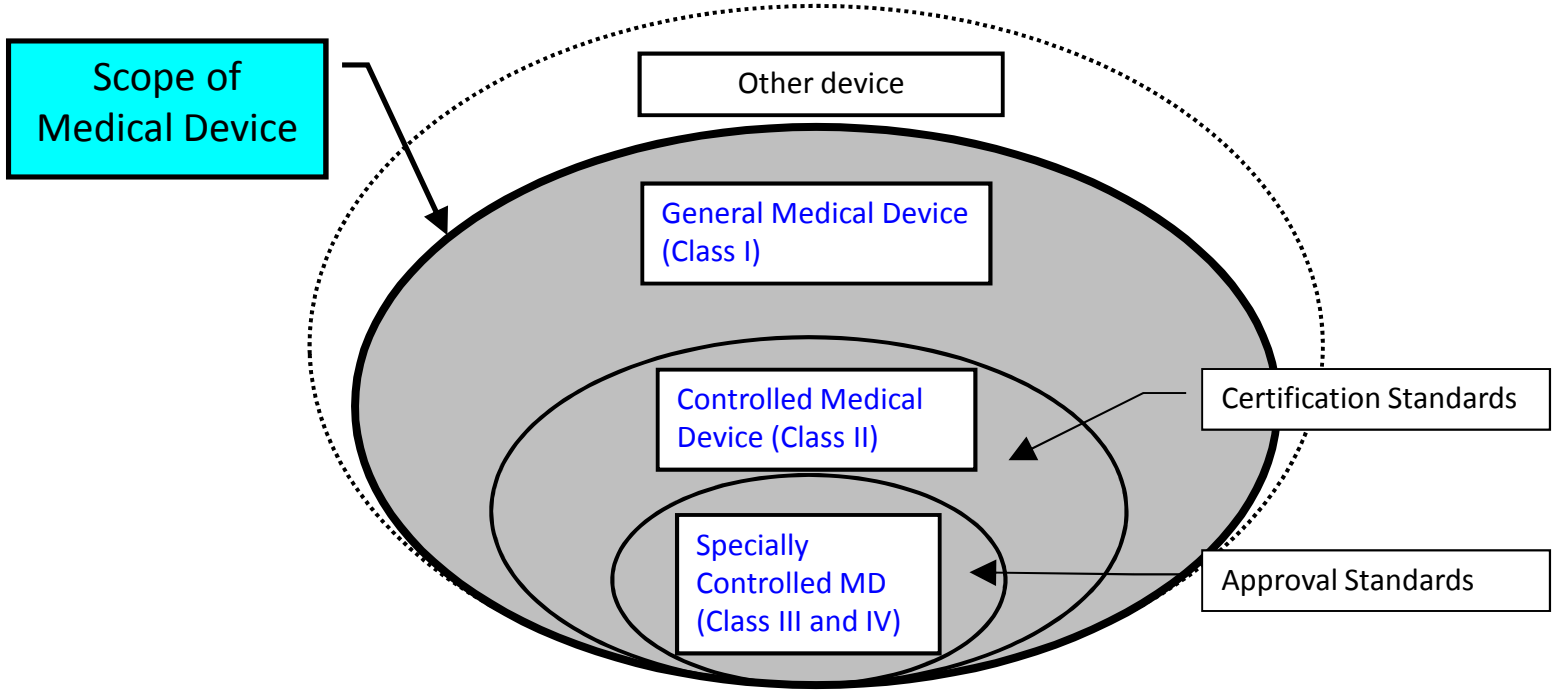
Notification on the amendment of the classification rule of medical devices, MHLW, May 10, 2013

It says on the top page, “The classification rule of medical devices has been stipulated based on the rule discussed in GHTF…”

And any other special rules has not been issued on the classification of medical device software. Therefore this rule should be applied for the medical device software.

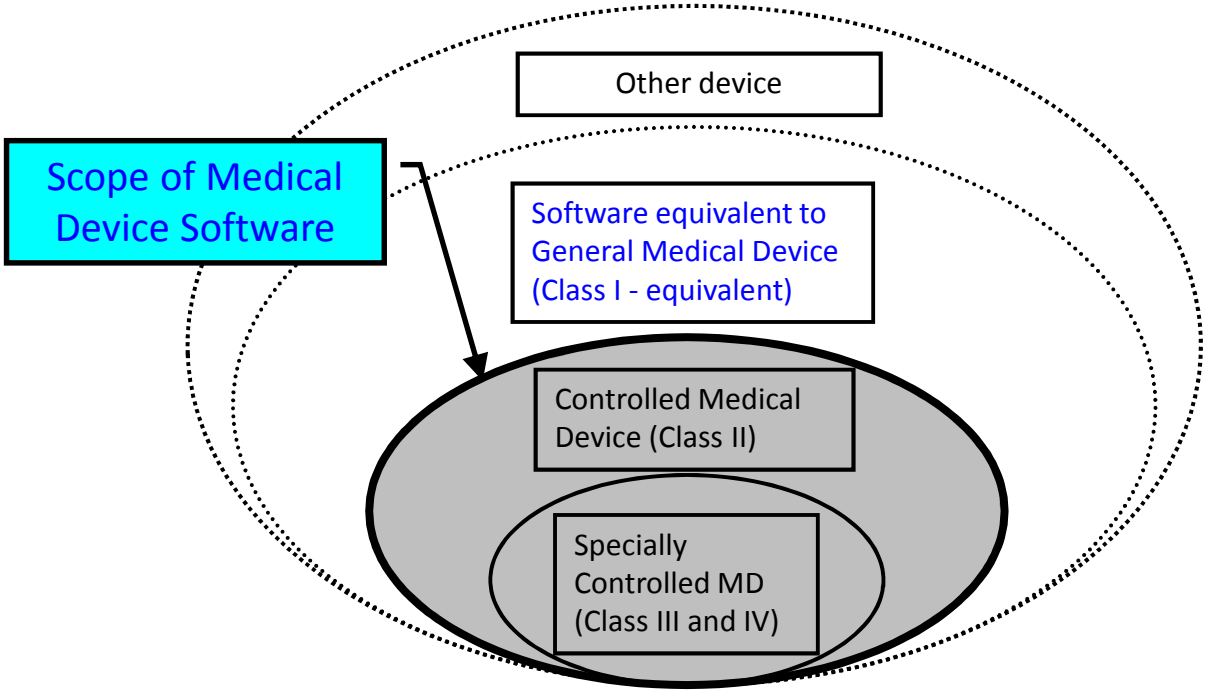
1-2. Classification of Medical Device Software

General classification of *Medical Device*



1-2. Classification of Medical Device Software

Scope of *Medical Device Software*



2-1. Low Risk Software

Software equivalent to Class I medical device

General Medical Device, Class I, has been eliminated from the medical device classification for software. It has little risk of affecting human life and health in case of the functional failure. This is the special classification rule only for the medical device software.

Example

1. Software which performs eyesight test or color perception test by general-purpose PC or handheld terminals
2. Software which detects body motion by means of sensors of handheld terminals

...

2-1. Low Risk Software

The approach of USA for low risk software
→ FDASIA Health IT Report, FDA, Apr., 2014

FIGURE 3: Overview of Proposed Health IT Priority Areas

2-2. Voluntary Standards by Private Sectors

What about Japan?

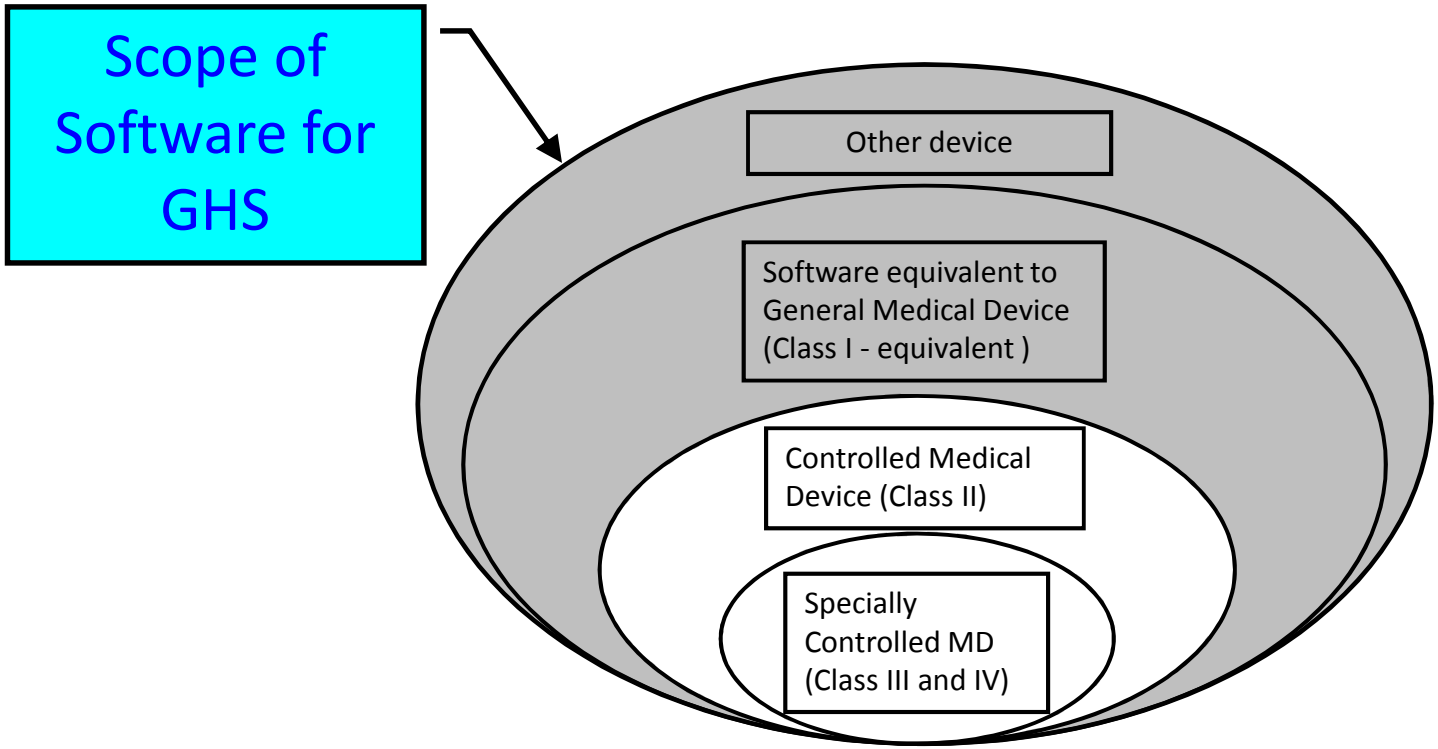
2-2. Voluntary Standards by Private Sectors

Good Health Software Promotion Council
for GHS（Good Health Software）

1. Purpose is to **develop guidelines for the non-medical device software** so that software developers can provide good software to users.
2. The guidelines are applied to **quality management, risk management, software product safety and software lifecycle process**. (GHS Development Guidelines)

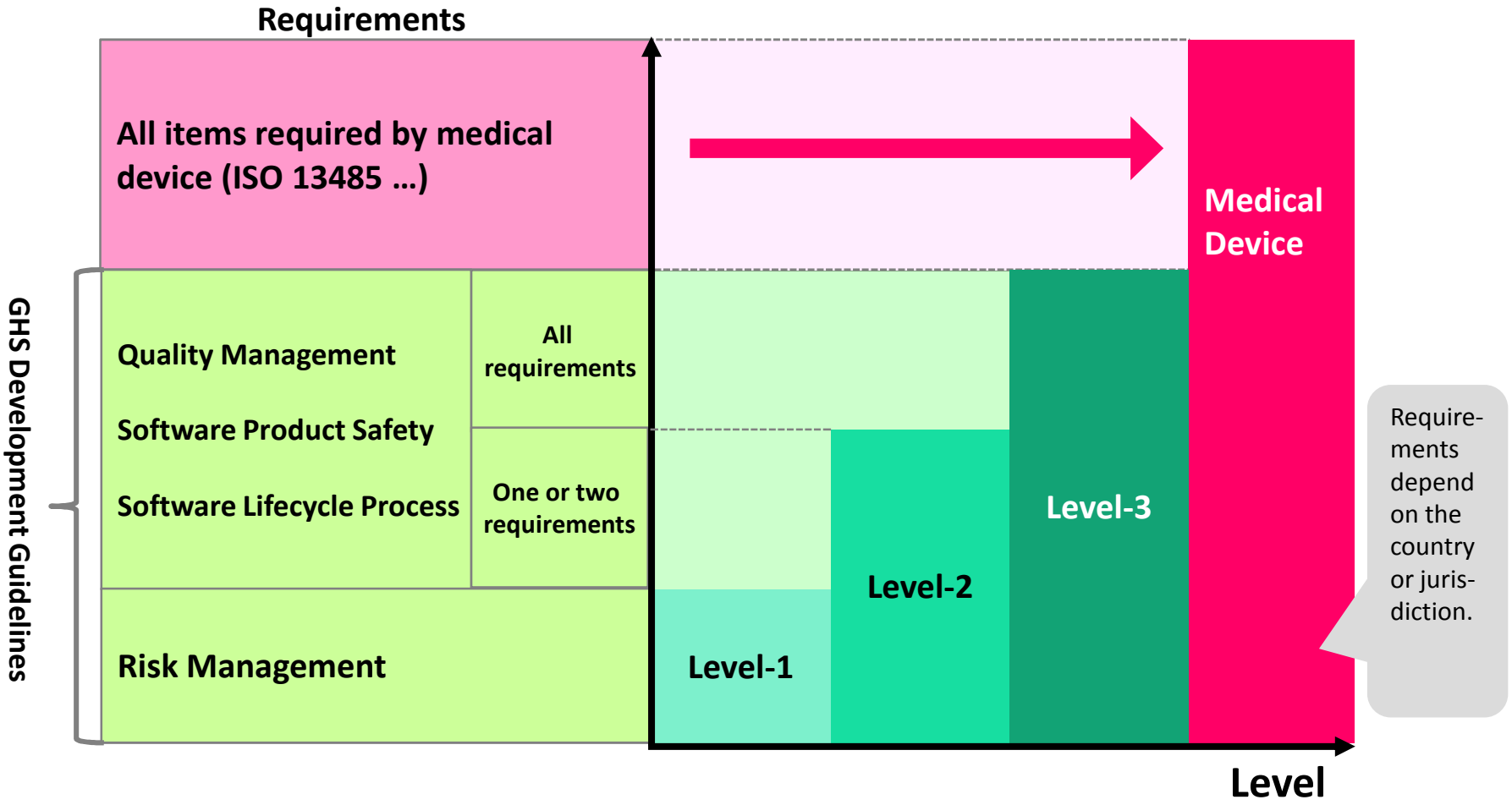
2-2. Voluntary Standards by Private Sectors

Scope of ***Software for GHS***



2-2. Voluntary Standards by Private Sectors

GHS Development Guidelines - Three conformance levels



2-2. Voluntary Standards by Private Sectors

The list of conforming software on the website

The items of the list are

- Level (Level-1, 2 or 3)
- Registration number
- Product name
- Software version
- Company name
- URL of company website

...

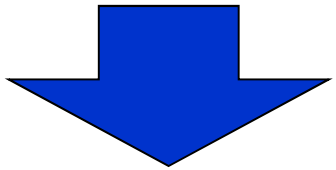
GHSマークの表示例		GHSマークの商標権について
GHS Level-1 G1400011	GHS Level-1 G1400011	GHSマークの商標権は一般社団法人ヘルスソフトウェア推進協議会が保有しています。GHSマークが不正に使用された場合には、当協議会はGHSマーク使用契約の解除その他必要な法的措置をとることができます。 また、GHSマーク適合の認定後、認定要件に対し適合が維持されていない場合には、当協議会は適切な是正措置を求めるとともに場合によっては認定の一時停止または取消を行うことがあります。

The list of conforming software

Level	登録番号	登録日	製品名	会社名	詳細
1	G1500011	2015-02-19	Product name	Company name	
1	G1500021	2015-02-19	Product name	Company name	
1	G1500031	2015-02-19	Product name	Company name	
1	G1500041	2015-02-19	Product name	Company name	
1	G1500061	2015-04-14	Product name	Company name	
2	G1500072	2015-04-14	Product name	Company name	
2	G1500142	2015-04-14	Product name	Company name	
2	G1500082	2015-04-14	Product name	Company name	
2	G1500092	2015-04-14	Product name	Company name	

3. Creating Certification Standards

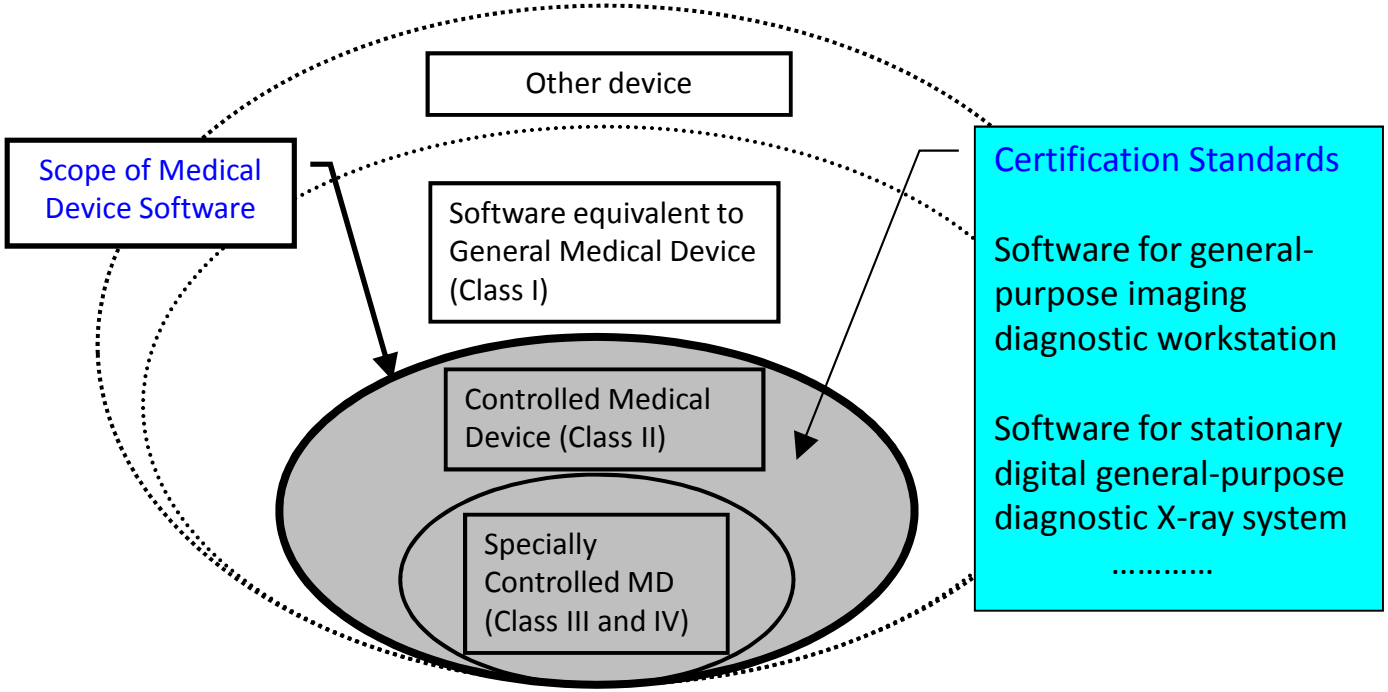
Qualification and classification rules have been stipulated. But it may take several years to have the devices reviewed by certification standards which require relatively short review term.



Expediting the premarket review process by creating the certification standards.

3. Creating Certification Standards

Scope of Medical Device Software



3. Creating Certification Standards

➢ Current innovative progress of medical device software is so drastic.
→ Creating every possible certification standard from hardware medical devices even though some standards may not be used.

● Certification Standards, 108 (total ~1370):
Name, applied standards, intended use and etc. All medical device software are Class II.

● JMDN (Japanese Medical Device Nomenclature), 150 (total ~4258):
Generic name, definition and etc. All medical device software with the certification standards are Class II.

* The numbers are as of 2014.

3. Creating Certification Standards

[Example]

The corresponding hardware medical device

JMDN Code: 70030000
Name: General-purpose imaging diagnostic workstation
Applied standard: JIS C 6950-1 (IEC 60950-1)
Intended use: It computerizes human image information from image diagnosis medical devices and provides processed image information for medical care (excluding those with automatic diagnostic functions)

Medical device software

JMDN Code: 70030012
Name: Software for general-purpose imaging diagnostic workstation
Applied standard: JIS C 6950-1 (IEC 60950-1)
Intended use: It computerizes human image information from image diagnosis medical devices and provides processed image information for medical care (excluding those with automatic diagnostic functions)

4. Pre-market Application and Validation

PMD Act employs basic concept of GHTF for essential principles of safety and performance of medical device.
→ **Essential Principles of Safety and Performance of Medical Devices, GHTF, Nov. 2, 2012**

Notification on the essential principles of safety and performance of medical device, MHLW, Nov. 5, 2014

One of the new requirements of the amendment is **the introduction of medical device software** and it requires to ensure the repeatability, reliability and performance according to the intended use. And the requirement in the event of a single fault condition is described. These requirements are also described in B8 of GHTF document.

4. Pre-market Application and Validation

Essential Principles Conformity Checklist is required for any medical devices.

Essential Principles Conformity Checklist is in tabular format of Essential Principles dedicated for the medical device with its related information such as applicability, applied standards, documentation information, etc. And **it is required to be included in the pre-market application document**.

4. Pre-market Application and Validation

Requirement for development lifecycle of software

Essential Principles
(Consideration of medical devices using programs)
Article 12
2 For devices which incorporate software the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, verification and validation to operate properly.

→ It will be mandatory that each application describes the conformity to the article in the application **from Nov. 25, 2017**.

4. Pre-market Application and Validation

Requirement for development lifecycle of software

How to describe the conformity to Article 12.2 in the application document

*(Now **in progress** of discussion within JFMDA to suggest MHLW)*

Report as the implementation status of development lifecycle

1. Summarizing the conformity to **JIS T 2304** with its implementation status.
2. Picking up some significant requirements of **JIS T 2304** with its conformity.
3. Listing up all the requirements of **JIS T 2304** in a tabular form.

5. Cybersecurity

Notification on cybersecurity, MHLW, April 28, 2015

1. Fundamental policy

MAHs should ensure cybersecurity by … **necessary risk control measures** …

2. Specific measures

(i) … perform **protective risk management** to evaluate and reduce the risks … **limiting the scope of connection** … and **limiting the software, system or services to those that are confirmed** …

(ii) … which necessary cybersecurity is not ensured, **the users should be clearly informed of this issue** …

(iii) In accordance with "Guidelines for the Security Management of Health Information Systems", **provide HDOs with necessary information** …

5. Cybersecurity

Guidance on how to implement the cybersecurity notification

*(Now **in progress** of discussion within JFMDA to suggest MHLW)*

- Scope

  Necessary consideration of cyber risk including network environment, intended use, operational environment, etc.

- Cybersecurity measurement

  Manuractures shall conduct risk management and demonstrate it is acceptable.

- Post-market safety assurance

  Manufactures are responsible for the cybersecurity of pre-owned devices.

- Providing information to users

  Manufactures shall provide necessary information to users to assure the safety of the device.

THANK YOU!