IMDRF International Medical Device Regulators Forum

Differences in device classification and authorization for AI/ML SaMD Industry experience

Sangjun Lee, AITRICS

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Medical Device Classification in Countries

- Medical devices are categorized into three to four classes globally.

South Korea	Japan	USA	Europe	Canada	Austrailia	Brazil	China	Russia	Singapore	Vietnam	Malaysia	Indonesia	Philippines	Saudi Arabia
MFDS	PMDA	FDA	MDR	Health Canada	TGA	ANVISA	NMPA	Roszdravnadzor	HSA	Ministry of Health	MDA	MoH	FDA	SFDA
Class I (1등급)	Class I (一般)	Class I	Class I	Class I	Class I	Class I (Baixo)	Class I (第一)	Class 1 (класс 1)	Class A	Class A (Loại A)	Class A (Kelas A)	Class A (Kelas A)	Class A	Class A (الفئة أ)
Class II (2등급)	Class II (管理)	Class II	Class IIa	Class II	Class Iia	Class II (Médio)	Class II (第二)	Class 2a (класс 2а)	Class B	Class B (Loại B)	Class B (Kelas B)	Class B (Kelas B)	Class B	Class B (الفئة ب)
Class III (3등급)	Class III (高度管理)	Class III	Class Iib	Class IiI	Class Iib	Class III (Alto)	Class III (第三)	Class 2b (класс 2б)	Class C	Class C (Loại C)	Class C (Kelas C)	Class C (Kelas C)	Class C	Class C (الفئة ج)
Class IV (4등급)	Class IV (高度管理)		Class III	Class IV	Class III	Class IV (Máximo)		Class 3 (класс 3)	Class D	Class D (Loại D)	Class D (Kelas D)	Class D (Kelas D)	Class D	Class D (الفئة د)

- These classes are determined by the safety and effectiveness of the medical device.

[South Korea's Criteria for Medical Device Classification]

- Class I: Medical devices with virtually no potential risk.
- Class II: Medical devices with low potential risk.
- Class III: Medical devices with moderate potential risk.
- Class IV: Medical devices with high potential risk.

The criteria for determining potential risk are as follows:

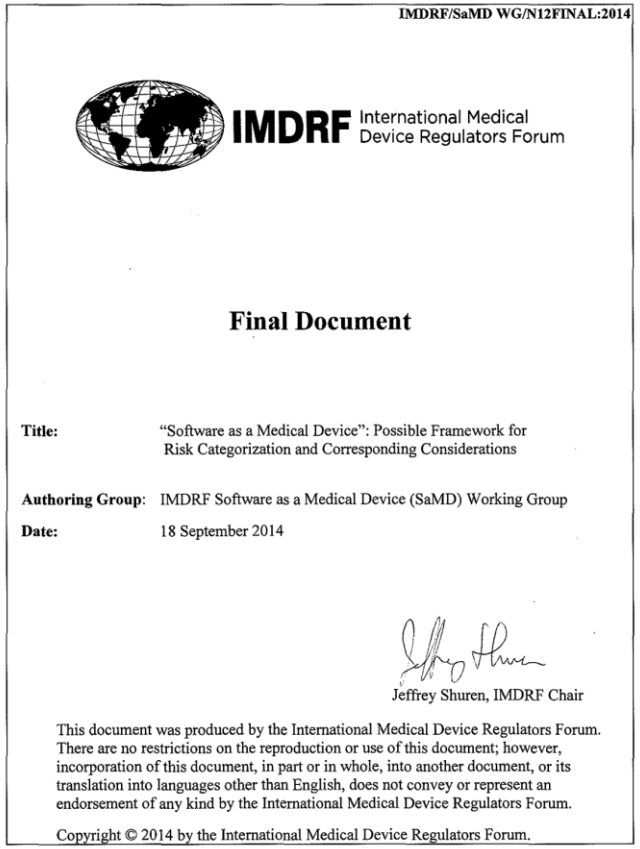
1. The duration of contact with the human body
2. The degree of invasiveness
3. Whether it delivers medicine or energy to the patient
4. Whether it has a biological effect on the patient

Changes of AI/ML MD Risk Classification - MFDS

- Detailed criteria for classification of digital medical devices by Digital Medical Products Act (MFDS)

Medical Situation or Patient Condition	Impact on Medical Care			Level of Direct/Indirect Harm from Performance Degradation or Malfunction
	Treatment·rehabilitation·examination·diagnosis·pharmaceutical support	Clinical management guide (prediction, prevention, etc.)	Information provision, management (monitoring) and others	
Critical·life-threatening (immediate, death within 24 hours)	4	3	2	Death (+1)
Serious (severe illness)	3	2	1	Severe injury - Minor injury
Non-serious (other illnesses)	2	1	1	No harm (-1)

SaMD Risk Classification in IMDRF



IMDRF/SaMD WG/N12FINAL:2014

IMDRF International Medical Device Regulators Forum

Final Document

Title: "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations

Authoring Group: IMDRF Software as a Medical Device (SaMD) Working Group

Date: 18 September 2014

Jeffrey Shuren, IMDRF Chair

- **SaMD Categorization** (p.14)

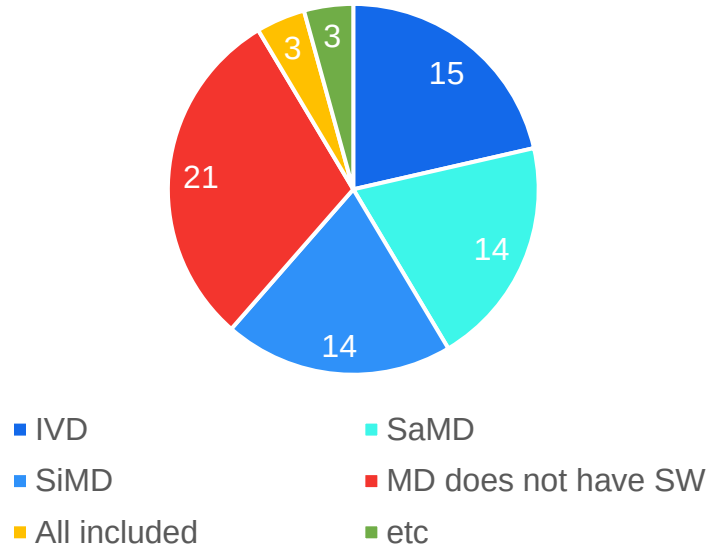
State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	4	3	2
Serious	3	2	1
Non-serious)	2	1	1

- SaMD categories are determined by the type of -
  - healthcare decision supported (treat/diagnose > drive management > inform management)
  - and the severity of the medical situation (critical > serious > non-serious).

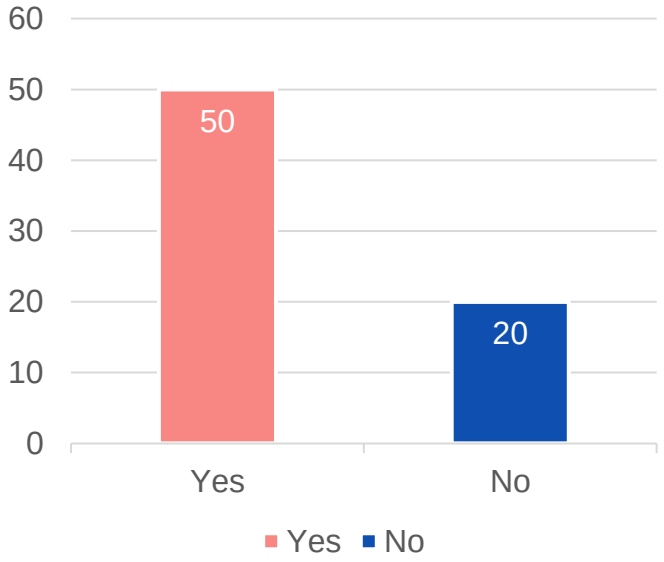
Industry Survey Result - Republic of Korea

- Survey on Experience with Differences in Medical Device Classification by Country
- Participate 70 medical device industry professionals in South Korea

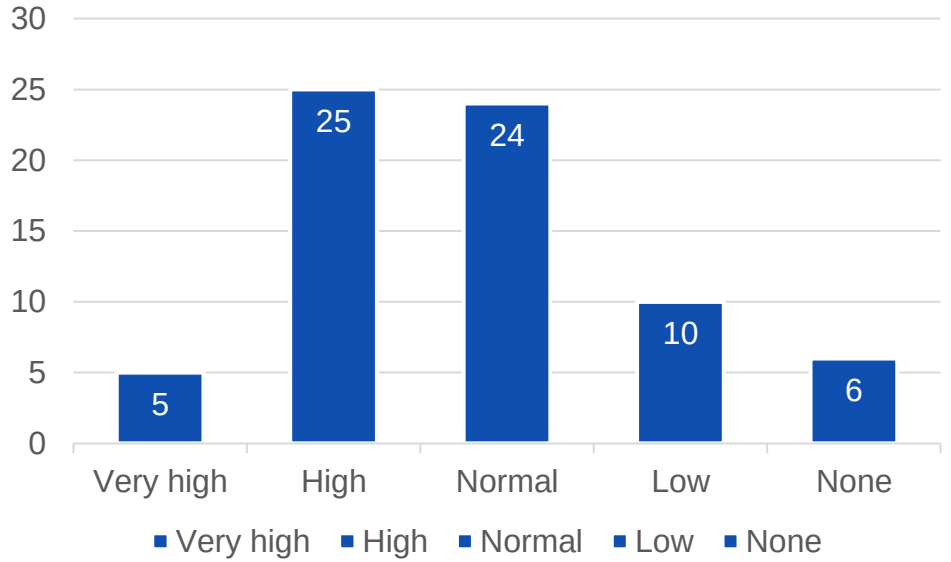
Manufacturer / Importer Type



Have you ever experienced a situation where the same medical device was classified differently in different countries?

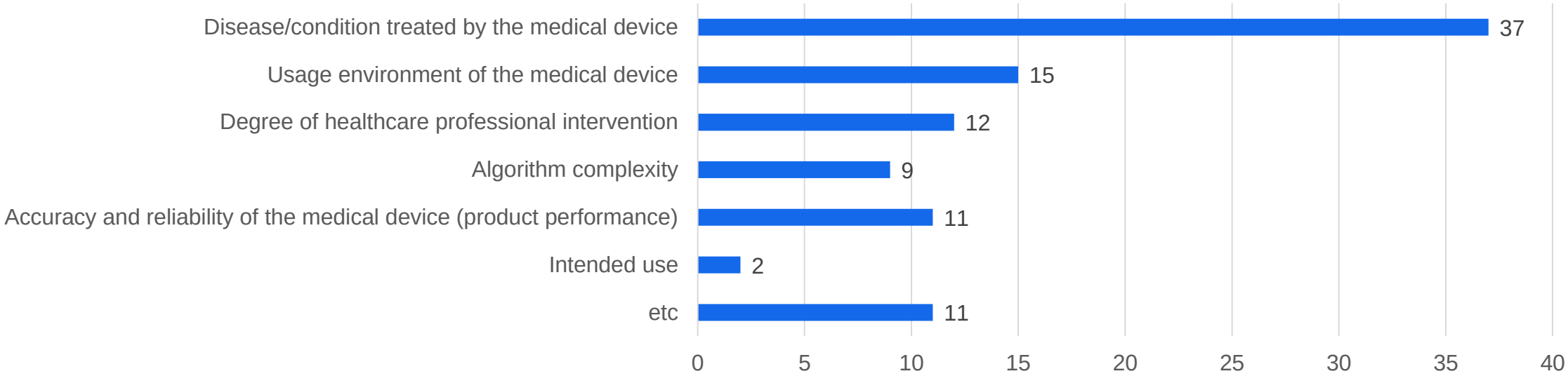


If you have experienced difficulties in formulating an approval strategy due to differences in classification across countries, to what extent?



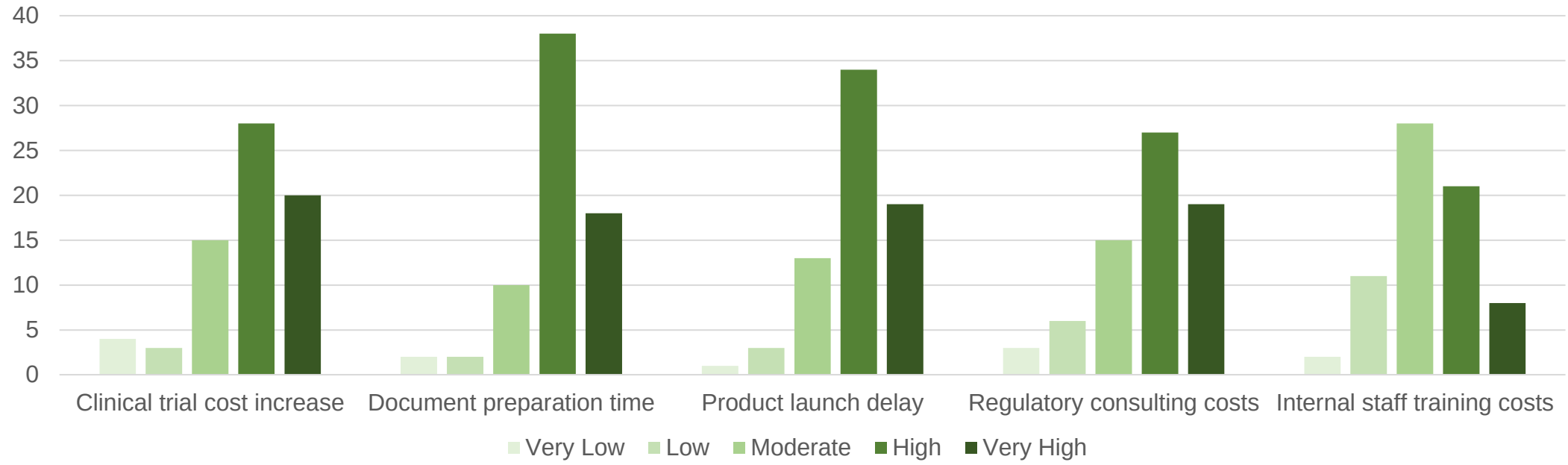
Industry Survey Result - Republic of Korea

- Q3. For AI-based medical devices, do you feel that the differences in classification grades between countries are greater than those for traditional medical devices?
  - **Strongly Agree (24%)** / **Similar (30%)** / Disagree (9%) / Strongly Disagree (1%) / Not Applicable (25%)
- Q4. Among the following characteristics, which do you think has the greatest impact on classification decisions by country? (**Multiple Selection**)



Industry Survey Result - Republic of Korea

- Q8. Please evaluate the burden level of the following items due to differences in classification between countries:



AITRICS Experience – Classification in AIML SaMD

Country A	Class II
Country B	Class III
Country C	Class II

Main feedback from countries that mentioned Class III: The diseases and environments addressed in the intended use correspond to a higher risk level in the country's medical device classification system.

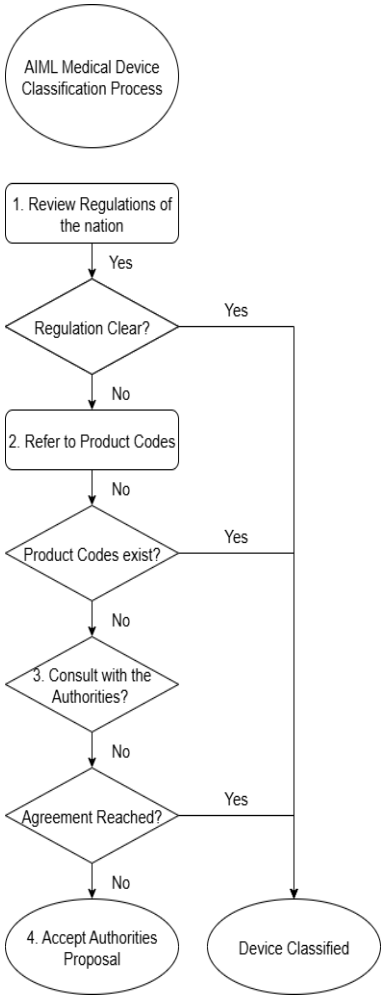
- 1 - Product Intended Use & Indications
  - Verify intended use
  - Confirm indications for use
- 2 - Device Classification by Jurisdiction
  - Check classification requirements
  - Review country-specific categories
- 3 - Regulatory Strategy
  - Option A: Consult national authorities
  - Option B: Proceed with internal classification
  - Submit based on determined class/category

After setting the classification by referring to the classification regulations of the respective country:

- If there are products with similar intended use in that country) Check the classification of those products
- If product categories are subdivided in that country) Check the classification of products within the product group

AITRICS Experience – Classification in AIML SaMD

- Determine the essential Intended Use for medical devices and apply the Classification specified in each country's regulations
    1. Review and apply the definitions and examples of Classes in the regulations
    2. If available, refer to and utilize the list of product codes for similar categories of devices already approved in the respective country
    3. Determine Classification by considering the risks associated with the device's **intended use, indications, and functions**, and consult with the authorities
    4. If the authorities reject the submitted Classification, accept the authorities' proposal as long as the intended use, indications, and key functions are not compromised



AITRICS Experience – Classification in AIML SaMD

- Important factors to review when classifying AI Medical Devices

1. User Scenario & Risk Management

- Focus on the entire Patient Workflow, not just the algorithm.
- Risk assessment must extend beyond the algorithm to the complete patient journey.

2. AI Assistant vs. AI Diagnosis

- Define the AI's role (assist a clinician's decision or make the diagnosis)

3. Human-AI Team

- Human-AI collaboration provides clinical benefits while mitigating the risks of AI.

Digital Health Product Classification

- **Traditional medical device vs Digital Health product**
  - The greatest challenge with Digital Health products is 'measuring the potential risk that products may cause to patients'
  - Additionally, some Digital Health products are difficult to classify as either medical devices or non-medical devices

LLM-based Digital Health Product

Age, Heartrate Monitoring Digital Health Product

Skin Analysis Digital Health Product

Steps to Harmonize Digital Health Device Classification Across Countries

- Develop standardized approaches based on intended use and clinical indications
- Enhance regulatory efficiency through international harmonization
- Build mutual reliance frameworks for classification decisions in digital health products

- Establishing digital health-specific classification criteria may help, but harmonization across countries requires coordinated international collaboration

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Thank you/Questions