IMDRF International Medical Device Regulators Forum

Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

Working group update

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IVD Working Group Chair

Roszdravnadzor

Russia

New Work Item Proposal

review and update the GHTF / SG1 / N045: 2008 document on
Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

Initiator
Russian Federation

- NWIP approved in March 2019 MC meeting in Moscow
- Working group formed and started working in June 2019

FIRST WORKING GROUP
PRIMARILY FOCUSED ON

IVD MEDICAL DEVICES

Working Group members

Australia: TGA
Michelle McNiven

Brazil: ANVISA
Fabio Pereira Quintino

Canada: Health Canada
Monica Magidin

China: NIFDC
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Yung-Chuan Lee
Razan Asally
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PAHO:
Mariela Aranda
Noaris Marquez
Marcia Rodriguez

New Work Item Proposal

- **Objective**

Review and update of GHTF/SG1/ N045:2008 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification based on modern state of development

- **Rationale**

new concepts and approaches have been emerged in laboratory diagnostics that are not reflected in the GHTF document (for example, genetic testing, companion diagnostics, SaMD, etc.)

- **Goal**

Increase in the harmonization and effectiveness of regulatory decision

Relevant existing documents

- 1. GHTF/SG1/N045:2008 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification.
- 2. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017.
- 3. Decision of the EEU Commission, dated 12.22.2015 № 173 “Rules for the classification of medical devices, depending on the potential risk of use”.
- 4. Medical Devices Regulations (SOR/98-282) (Canada).
- 5. Classification of IVD medical devices, December 2015, TGA (Australia).
- 6. Guidance on the Risk Classification of In Vitro Diagnostic Medical Devices, June 2018, HSA (Singapore).
- 7. Resolution RDC № 36/2015, Article 4, IVD Classification Rules, ANVISA (Brazil).
- 8. AHWP/WG2/F001:2016 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification” for format consistency with item 1.
- 9. Risk based classification of diagnostics for WHO Prequalification, May 2014, WHO

Working progress

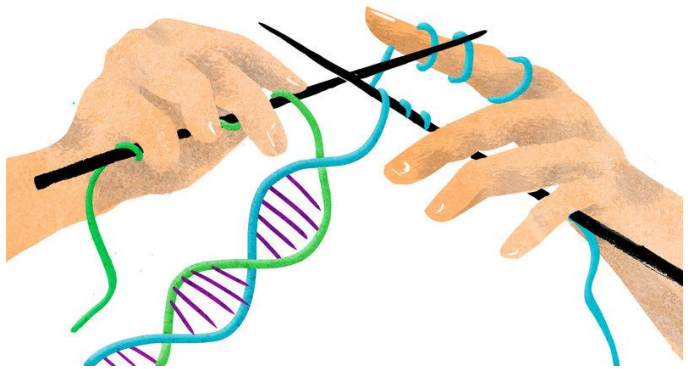
NWIP APPROVAL
March 2019

First WG Tconf
June 2019

First face-to-face meeting in Moscow
Aug 2019

First Working Draft
Sept 2019

Second WG TConf
(*to be confirmed*)



Risk-based Classification

created by the Global Harmonization Task Force (GHTF)

Classification general approach

IV classes

A, B, C, D

Criteria: individual and public health risk level

		PUBLIC		
		Low	Moderate	High
INDIVIDUAL	Low	A	B	None
	Moderate	B	B	C
	High	C	C	D

7 rules

Criteria: intended use, specific characteristics

Risk-based classification was primarily created

- ❑ To:
determine the level of pre-market regulatory assessment that is required for an IVD medical device

- ❑ For:
regulatory control to be sufficient for each risk class to safeguard the health and safety of patients, users and other persons

- ❑ Outcome:
grouping IVDs into one of four classes representing increasing individual and public health risk

GHTF / SG1 / N045: 2008 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

Changes in Working Draft

- General approach maintained
- Rules modified considering modern technologies
- Added Definitions
- Updated references
- Added examples
- Structured

Main discussed points:

- Accessories` definition;
- SaMD classification;
- differentiation of “research use only” medical devices;
- Possible class changes while implementation

Current status

- Clear version of first WD is under WG consideration
- First comments received from Japan, EU, Canada and China

The “Process”

General plan and time schedule

Submission of a draft document to the MC to approve its placement for public consultation

March 2020

Adoption of the final version

September 2020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