Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

Working group update

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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
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<thead>
<tr>
<th>Country</th>
<th>Organization</th>
<th>Name(s)</th>
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<tbody>
<tr>
<td>Australia</td>
<td>TGA</td>
<td>Michelle McNiven</td>
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<tr>
<td>Brazil</td>
<td>ANVISA</td>
<td>Fabio Pereira Quintino</td>
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<td>Canada</td>
<td>Health Canada</td>
<td>Monica Magidin</td>
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<td>NIFDC</td>
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<td>Sigrid Nick</td>
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<td>Japan</td>
<td>PMDA</td>
<td>Hiromi Yamada, Eri Orihara, Mika Togashi, Yasuyuki Sakurai</td>
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<td>Singapore</td>
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<td>Rama Sethuraman, Danny Ong</td>
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<td>Wen-Wei Tsai, Yung-Chuan Lee, Razan Asally, Mariammah Krishnasamy</td>
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<td>Mariela Aranda, Noaris Marquez, Marcia Rodriguez</td>
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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.
- 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).
- 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.
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

Classification general approach

IV classes
A, B, C, D
Criteria: individual and public health risk level

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7 rules
Criteria: intended use, specific characteristics

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

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
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
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
THANK YOU