Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

Progress report

March 23
2021

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Roszdravnadzor
Moscow, Russia
<table>
<thead>
<tr>
<th>Country</th>
<th>Organization</th>
<th>Members</th>
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<tbody>
<tr>
<td><strong>Australia</strong></td>
<td>TGA</td>
<td>Antje Janssen, Michelle McNiven</td>
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<td><strong>Brazil</strong></td>
<td>ANVISA</td>
<td>Fabio Pereira Quintino</td>
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<td><strong>Canada</strong></td>
<td>Health Canada</td>
<td>Monica Magidin</td>
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<td><strong>China</strong></td>
<td>NIFDC</td>
<td>Ying Huang, Le Cui</td>
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<td><strong>European Union</strong></td>
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<td>Heiner Scheiblauer, Gaelle Lebrun, Nada Alkhayat</td>
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<td><strong>Japan</strong></td>
<td>PMDA</td>
<td>Hiromi Yamada, Eri Orihara, Mika Togashi, Yasuyuki Sakurai</td>
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<td><strong>Russia</strong></td>
<td>Roszdravnadzor</td>
<td>Tatyana Buryakina, Vladimir Antonov, Roman Bystrov</td>
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<td><strong>Singapore</strong></td>
<td>HSA</td>
<td>Rama Sethuraman, Danny Ong</td>
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<td><strong>South Korea</strong></td>
<td>MFDS</td>
<td>Yong-kyoung Lee, Hye-jin Hwang, Hyo-jin Kim</td>
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<td><strong>USA</strong></td>
<td>FDA</td>
<td>Dina Jerebitski</td>
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<td><strong>WHO</strong></td>
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<td>Irena Prat, Helena Ardura</td>
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<td><strong>AHWP</strong></td>
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<td>Wen-Wei Tsai, Yung-Chuan Lee, Razan Asally, Mariammah Krishnasamy</td>
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<td><strong>PAHO</strong></td>
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<td>Mariela Aranda, Noaris Marquez, Marcia Rodriguez</td>
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<td><strong>Industry (GMTA)</strong></td>
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<td>Danelle Miller, J.D., Masaki Sakakibara, Petra Kaars-Wiele</td>
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Public consultations

63 comments from public consultation
Over 200 comments and corrections by WG

Comments compiled to the table – each comment had it’s discussion and resolution

Approved changes included in the text

More than 20 WG members participated in weekly Teleconferences
Overall progress

- **Online progress report**
  - **WG TConf**
  - **March 2020**
  - **Nov-Dec 2019**

- **Extended deadline for public comments**
  - **July 25 2020**

- **Weekly WG TConferences**
  - **Aug – Dec 2020**

- **Approval of the final document**
  - **Jan 2021**

- **IMDRF/IVD WG/N64 FINAL:2021 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification**

- **APPROVED January 2021**
Next steps

IMDRF/GHTF documents Systematic Review

- Approved by MC – review and update
- Proposal formulation
- IVD WG discussions (e-mails exchange)
- Teleconferences (draft discussion)
- Final version of NWIP + discussion with MDCE
- Further Teleconferences upon NWIP approval

NWIP on GHTF documents review and update – to be formed

Collaboration with MDCE
Future work

New Work Item Proposal

Review and update of:

- GHTF/SG5/N6 (Clinical Evidence for IVD Medical Devices-Key Definitions and Concepts)
- GHTF/ SG5/N7 (Clinical Evidence for IVD Medical Devices-Scientific validity determination and Performance Evaluation)
- GHTF/SG5/N8 (Clinical Evidence for IVD Medical Devices-Clinical Performance studies for IVDs)

Collaboration with MDCE WG
Proposal to be approved by MC
THANK YOU FOR YOUR ATTENTION!