



Principles of In Vitro Diagnostic
(IVD) Medical Devices
Classification
Working group update

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Working Group members

Australia: TGA

Michelle McNiven

Brazil: ANVISA

Fabio Pereira Quintino

Canada: Health Canada

Monica Magidin

China: NIFDC

Ying Huang

Le Cui

European Union: Paul-Ehrlich Institute

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Mika Togashi

Yasuyuki Sakurai

Russia: Roszdravnadzor

Tatyana Buryakina

Vladimir Antonov

Roman Bystrov

Singapore: HSA

Rama Sethuraman

Danny Ong

South Korea: MFDS

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Hyo-jin Kim

USA: FDA

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WHO:

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Helena Ardura

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Wen-Wei Tsai

Yung-Chuan Lee

Razan Asally

Mariamamah Krishnasamy

PAHO:

Mariela Aranda

Noaris Marquez

Marcia Rodriguez



Working Group new members

Industry representatives

Danelle Miller, J.D. (Global Regulatory Policy and Intelligence,
Roche Diagnostics)

Masaki Sakakibara (Regulatory Affairs Division, SYSMEX
Corporation)

Petra Kaars-Wiele (Independent Consultant, Germany)



IMDRF

International Medical
Device Regulators Forum

Working progress





IMDRF

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Public consultations

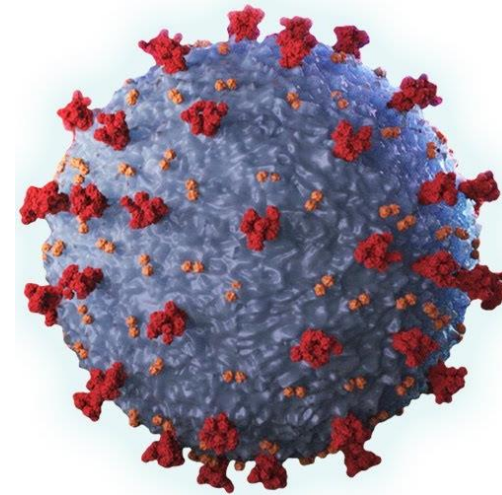
Comments compiled to the table – each comment had it's discussion and resolution

Approved changes included in the text

Further discussion on the comments and finalizing the wording.

Additional discussion still needed

63 comments received



More than **20** WG members participate in each weekly
TConference



IMDRF

International Medical
Device Regulators Forum

Plan and time schedule

WG discussion and finalizing the final draft



Adoption of the final version

January 2020 Teleconference

(upon MC approval)

or March 2021



IMDRF

International Medical Device Regulators Forum

THANK YOU

GRACIAS
ARIGATO
SHUKURIA
JUSPAXAR
DANKSCHEEN
СПАСИБО
TASHAKKUR ATU
SUKSAMA
EKHMET
MERBANI
PALDIES
BOLZIN
MERCIE
BIYAN
SHUKRIA
TINGKI
HATUR GU
SIKOMO
MAKETAI
MINMONCHAR

SPASSIBO
SNACHALHUYA
CHALYU
YAQHANYELAY
YUSPAGARATAM
WABEEJA
MAITEKA
HUI
UNALCHEESH
ATTO
DHAHYABAD
AHNIA
MERSI
SPASIBO
DENKAUJA
NENACHALHYA
SANCO
MERASTAWHY
GAEJTTHO
AGUYJE
FAKAAUE
KOMAPSUMNIDA
MAAKE
LAH
MAMETAI