



New Work Item Proposal IVD Working Group

September 2021

Tatyana Buryakina, PhD

IVD Working Group Chair

Roszdraznadzor

Moscow, Russia



Finished project

Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

Posted at IMDRF website, 2021

IMDRF/IVD WG/N64FINAL:2021 (formerly GHTF/SG1/N045:2008)

Planned project

New Work Item Proposal

New Working Group to be formed



Purpose

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)

