Global Medical Technology Alliance
Innovating for a Healthier World

IMDRF Harmonized Unique Device Identification (UDI) Application Guide

GS1 Global Conference - Bogota, Colombia

April 12, 2018

Jackie Rae Elkin, Medtronic

- IMDRF is a **voluntary group of medical device regulators from around the world** who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and **aims to accelerate international medical device regulatory harmonization and convergence.**

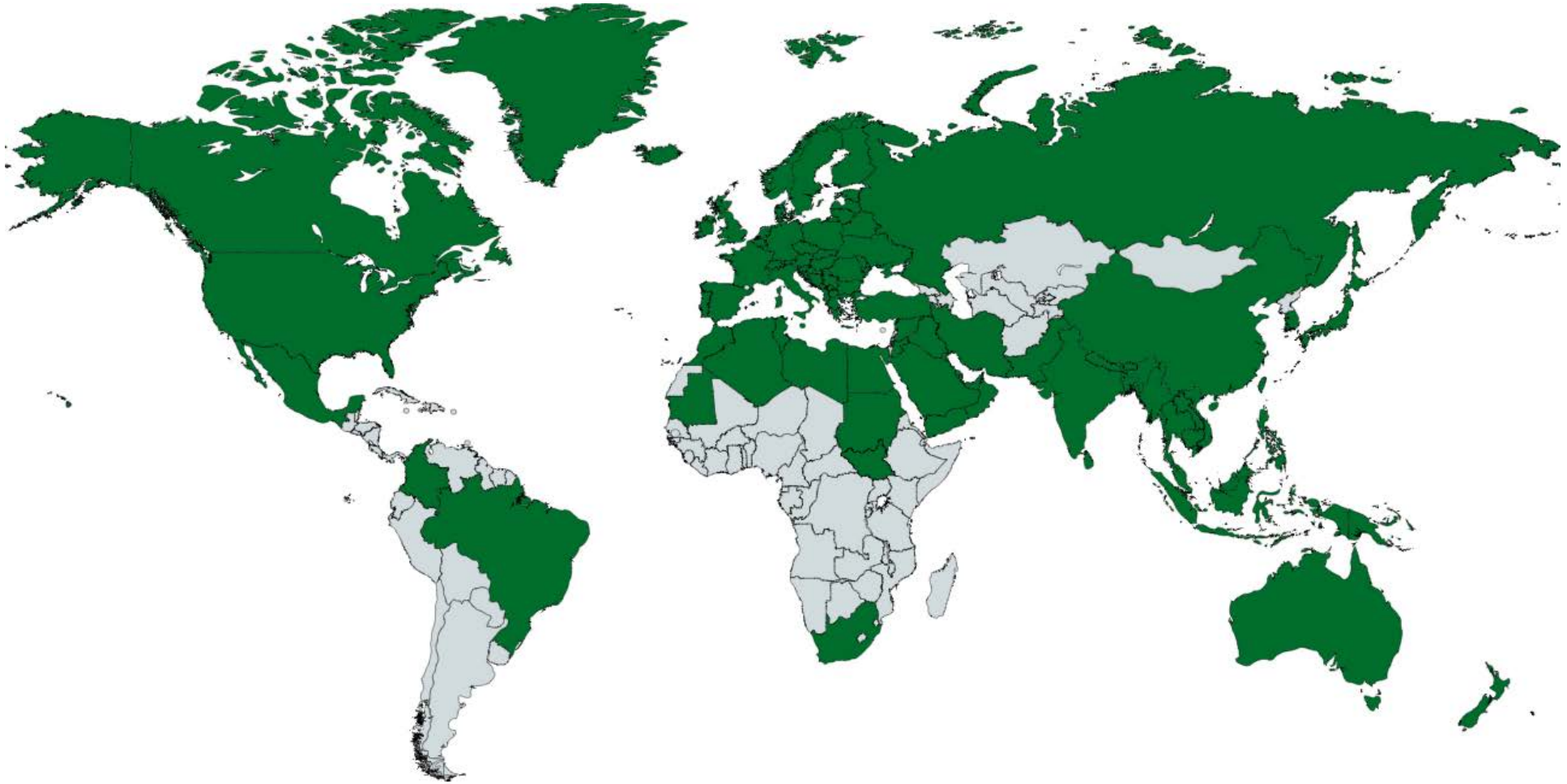
GMTA is the Global Medical Technology Alliance. **Its members are national or regional medical technology associations**, which represent innovative **companies that currently develop and manufacture 85 percent of the world's medical devices**, diagnostics and equipment. It **provides a forum for the development and advocacy of policies that support innovation in medical technology to address patients' healthcare needs**. Medical technologies save, support, and improve lives every day around the world.

Global Medical Technology Alliance

Innovating for a Healthier World

- Origins date to **1990s as informal network**
- **Formally established in 2010 with Secretariat and website in Geneva**; legally constituted in Switzerland as an “association” in 2013; WHO recognized NGO in 2015
- Membership open to **medical technology associations** (not companies):
  - Willing to accept GMTA governance rules
  - With functioning code of ethical business practices

25 Member Associations Around the World



Background of the NWIP

- New Work Item Proposal (NWIP) for **Harmonized UDI Application Guide** presented at March 2017 IMDRF Management Committee meeting
- Management Committee instructed **GMTA to prepare first draft** of the IMDRF UDI Application Guide
- **Draft submitted July 7, 2017**
- **September 2017 - Management Committee Approved** NWIP (with revisions), EU Chair

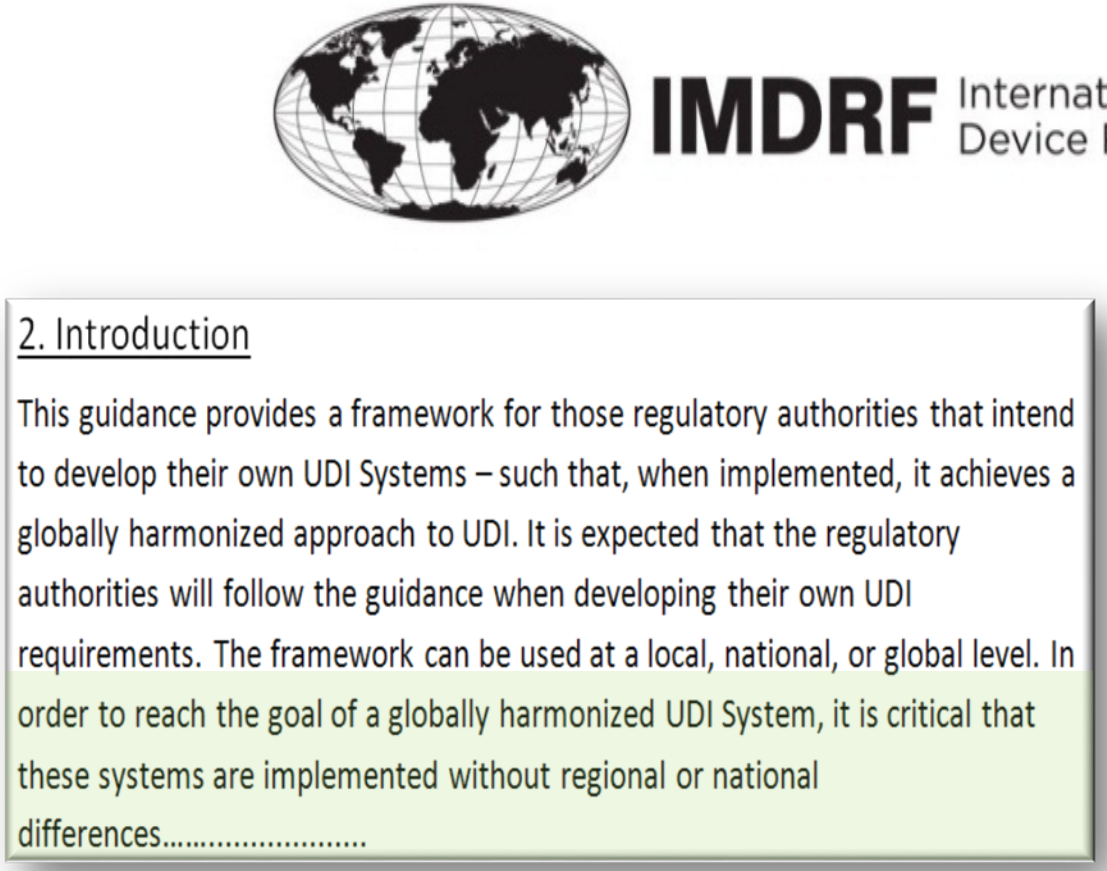

IMDRF International Medical Device Regulators Forum
PROPOSED WORKING DRAFT
International Medical Device Regulators Forum
Title: Unique Device Identification (UDI) Application Guide

Scope of Draft

- **Extension of original IMDRF UDI Guidance**
- Provide details and specifications **necessary to enable harmonized UDI approaches**
- **Builds on work** carried out at national levels
- **Not redefining content or requirements** of original IMDRF UDI Guidance of 2013

INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM (IMDRF) UDI WORK GROUP

IMDRF International Medical Device Regulators Forum



2. Introduction

This guidance provides a framework for those regulatory authorities that intend to develop their own UDI Systems – such that, when implemented, it achieves a globally harmonized approach to UDI. It is expected that the regulatory authorities will follow the guidance when developing their own UDI requirements. The framework can be used at a local, national, or global level. In order to reach the goal of a globally harmonized UDI System, it is critical that these systems are implemented without regional or national differences.....

UDI WG Established under Global Harmonization Task Force (GHTF) October, 2008.

IMDRF Guidance
UDI for Medical Devices
Final Version,
December 9, 2013

http://www.imdrf.org/documents/documents.asp

Key Sections of Draft

- Fundamental Elements of a Harmonized UDI System
- Develop a Standardized System of Unique Device Identifiers (UDIs)
- Guiding Principles for UDI System Design and Operation
- Content and Structure of a UDI
- Establishing Responsibility for Creating and Maintaining a UDI System

Key Sections of Draft

- Representation of UDI in Human Readable Interpretation and Auto Identification Data Capture (AIDC) Formats on the Package Label and in Some Cases, on the Device Itself
- The Unique Device Identification Database (UDID)
- General Considerations to Facilitate an Effective transition to UDI Application
- Special Device Types

UDI WG Schedule

- Kick-off WG December 2017
- Workshop / initial face-to-face meeting - February 2018
- Submission of draft guide to Management Committee for approval for public consultation – May 2018
- Consultation period of three months
- Work Group consultation comments review
- **Final submission to Management Committee end of 2018 – beginning of 2019**

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THANK YOU!

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