The Global Language of Business

Global Medical Technology Alliance discussing International Medical Device Regulators Forum (IMDRF)

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GMTA

IMDRF Harmonized Unique Device Identification (UDI) Application Guide

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Jackie Rae Elkin, Medtronic

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.

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IMDRF International Medical Device Regulators Forum

Background

- 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), “Harmonized Unique Device Identifier (UDI) Application Guide” (EU to chair).

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IMDRF International Medical Device Regulators Forum

New Work Item Proposal (NWIP)
For Management Committee consideration

Proposed Title of the Project	**IMDRF Harmonized Unique Device Identification (UDI) Application Guide**
Initiator	Global Medical Technology Alliance (GMTA)
Purpose and Rationale (including a reference to one or more of the goals or objectives of the IMDRF)	**Purpose** To promote a globally harmonized approach to the application of a UDI system in support of the IMDRF UDI Guidance Document (IMDRF/WG/N7Final:2013)

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WORK ITEM PROPOSAL

To develop an Application Guide for UDI that will **facilitate implementation of a globally harmonized approach to UDI** with a focus on:

- general UDI **assignment** rules
- **structure and format** of UDI
- data specifications for the Device Identifier (DI) **Core Data Elements** to be transmitted to UDI databases around the globe
- general principles for **exceptions or alternatives** for UDI

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RATIONALE

- A global UDI system is intended to provide a single, globally-accepted system for positive identification of medical devices. The IMDRF UDI Guidance document **does not contain the level of detail needed for a globally harmonized approach to the implementation** of a UDI system.

- Introduction of the IMDRF UDI Guidance IMDRF "This guidance is intended to provide a high-level conceptual view of how a global UDI System should work. **It is recognized that further additional guidance may be needed once these core concepts are accepted**." (IMDRF/WG/N7Final:2013)

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PROPOSED SOURCES OF NECESSARY EXPERTISE

- The work of this proposal will **build upon the work and expertise of IMDRF UDI Working Group** and will require involvement from both IMDRF regulators and industry UDI SMEs.

- The Work Group should include the members of the IMDRF UDI WG at the completion of the Final Guidance (IMDRF/WG/N7Final:2013)

Proposed Working Group Chair: European Commission

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OPPORTUNITIES FOR REGULATORY CONVERGENCE

- The work of this group will **build upon the work carried out at national level** on UDI systems (US and EU).

- In the spirit of moving the work item forward in an expedient manner, the **GMTA industry group will provide a preliminary working draft** of the application guide for review and edit by the IMDRF UDI Work Group regulators.

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PROPOSED WORK PLAN

- ❑ Formation of the Work Group
- ❑ Review preliminary working draft of UDI Application Guide provided by GMTA industry members
- ❑ Further develop Application Guide and associated technical specifications
- ❑ Publish Application Guide for Public Consultation
- ❑ Analysis of Consultation Contributions
- ❑ Draft proposal of UDI Application Guide to the IMDRF-MC

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GMTA PROPOSED WORKING DRAFT

IMDRF International Medical Device Regulators Forum

PROPOSED WORKING DRAFT

International Medical Device Regulators Forum

Title: Unique Device Identification (UDI) Application Guide

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Scope of Draft

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

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Key Sections of Draft

- Establishing a standardized UDI system
- HRI format, structure, and placement
- Applying UDIs to package level structures
- Direct marking of UDI
- Submission of UDI elements to database
- Adjudication process for alternatives

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Items Not Addressed in Draft

- Issues surrounding multiple DIs
- Exceptions to UDI requirements
- Items inconsistent with national-level rules
- Issues better left for IMDRF UDI WG
- Specificity requiring decisions by and agreement of the Regulators

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THANK YOU!

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