New Work Item Proposal (NWIP)  
For Management Committee  
Consideration

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PROPOSED TITLE:
IMDRF Harmonized Unique Device Identification (UDI) Application Guide

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)
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 marking when feasibility is an issue
RATIONAL

- 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

  “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)
PROPOSED SOURCES OF THE 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
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.
PROPOSED WORK PLAN

- Formation of the Work Group
- Review preliminary working draft of UDI Application Guide provided by GMTA industry members
- Further develop Functional User Requirements
- Develop Technical Specification of the Application Guide
- Publish Application Guide for Public Consultation
- Analysis of Consultation Contributions
- Draft proposal of UDI Application Guide to the IMDRF-MC