



**IMDRF**

International Medical  
Device Regulators Forum

**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



## 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 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



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Thank You