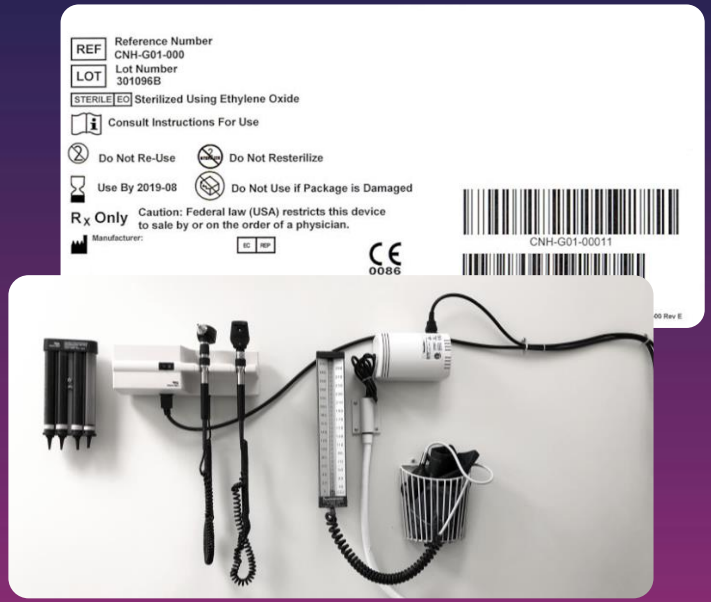
Rimsys | RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY

RAPS Ask an Expert

Everything you need to know about UDI



What we'll cover today

Agenda

- A quick UDI overview
- Your questions
- That's it

Rimsys Panelists

James Gianoutsos
Founder & CEO

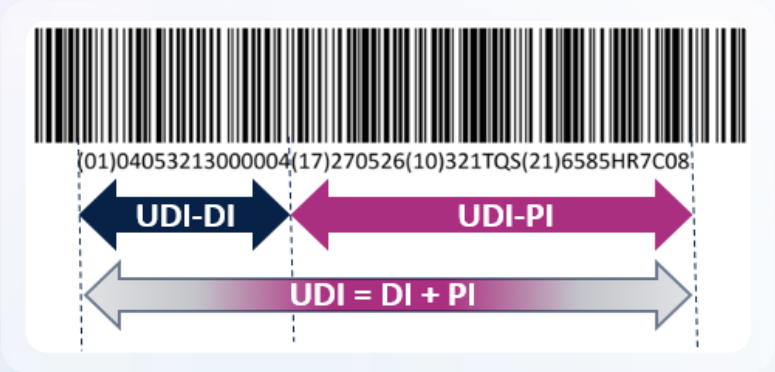
Bruce McKean
Director of Regulatory

Adam Price
Director of Technical Programs

What is UDI?

Unique device identifier (UDI): Is a unique numeric or alphanumeric code that consists of the following characteristics:

- Device identifier (DI)
- Production identifier (PI)
- *Basic UDI-DI (BUDI), EU only*
- *Master UDI-DI, EU only*
- Human readable
- Machine readable
- Accredited issuing entity
- Placed on devices, packages, or directly on the device (Direct Marking = DM)
- Data elements registered within a country specific database



UDI is more than just a bar code

Why UDI?

- Increases traceability of medical devices
- Provides unambiguous identification method throughout distribution and use, prevents counterfeiting
- Effective management of post-market safety-related activities (i.e., adverse event reporting and device recalls)
- Improves device documentation and reduces medical errors by healthcare professionals

Traditionally UDI has been handled separately from other regulatory information or processes

UDI and the EUDAMED database are key components of MDR/IVDR regulations in the EU

New device classification rules

Required re-certification to retain market approvals

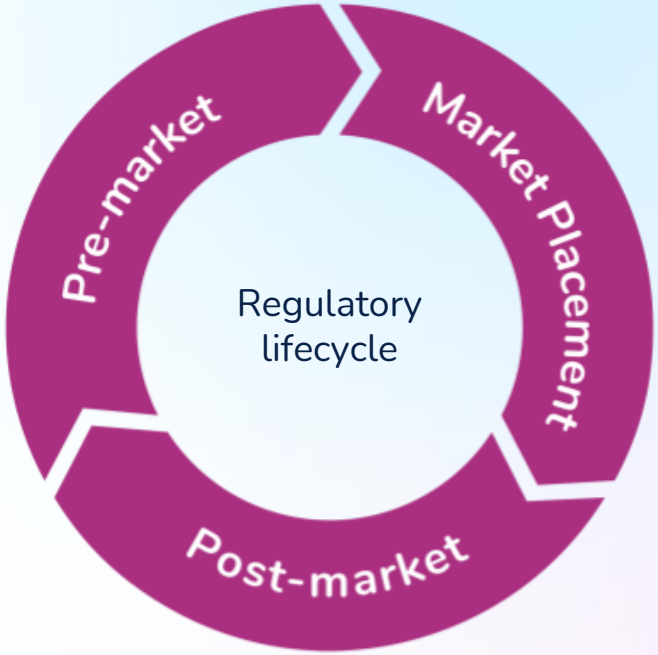
Expanded technical files & GSPRs

UDI & labeling

Centralized device & report database (EUDAMED)

Post-market surveillance & reporting

Why is UDI a regulatory concern?



Pre-market

UDI is part of design controls, and regulatory submissions. Products cannot be registered without it

Market Placement

Manufacturers are responsible to ensure that all submitted UDI information is current and up to date

Post-market

UDI is contained in Vigilance and Post Market Surveillance Reports

Q&A

Ask us anything about UDI



Additional resources:

- Quick reference guide – Global medical device UDI requirements and timelines
- The ultimate guide to the EU MDR/IVDR UDI system
- The ultimate guide to the China UDI system and database

RAPS Euro Convergence

Find Rimsys at booth B13

Join our session: *Clearing up EUDAMED confusion for medtech regulatory teams* May 7: 13:10-13:40