



# projektraum36

How to achieve continuous  
worldwide UDI Compliance

July 1, 2020

# What is Unique Device Identification (UDI)?



Worldwide Unique Identification  
of Medical Devices



Improve Patient Safety



Improve Recall Processes



Improve Market Surveillance

# The global UDI Challenge



## Our UDI Platform mission

„Deliver the best **UDI governance solution** on the market – based on deep UDI expertise, cloud focus and long-term commitment to our customers.“

# UDI Platform solution approach

## 1 SAP Cloud-based

- SAP as trusted and reliable Platform Provider
- Various Integration technologies available
- Efficient Change management for externally driven requirements

## 3 Configure, don't code

- Design & configure UDI processes (Low code)
- Flexible Workflows and User Interfaces
- Cross-Market Reporting and Audit Trail



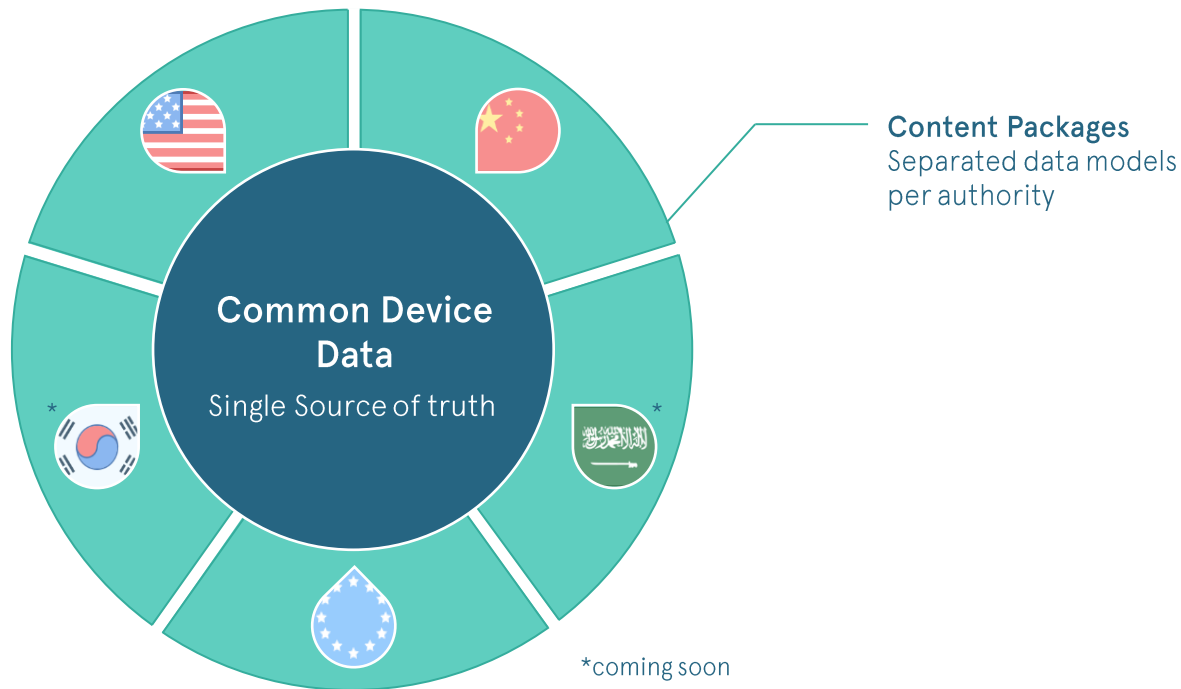
## 2 Expand to other countries

- Common Device Model & Multi-Agency-Capability
- Extend to other countries: Content Packages containing the specific data model & data validation rules
- Includes Submission interface

## 4 Managed Service

- Market Monitoring
- Change Implementation
- New requirements
- Continuous Compliance Support

# One Platform for worldwide UDI compliance



# UDI Platform governance & submission process



My Inbox  
Expert View

98

Device Management

Device Group  
Manage Device Group...

Device  
Manage Device Data

EU - EUDAMED

Basic UDI-DI Request (IVDR) EUDAMED

Basic UDI-DI Request (MDR) EUDAMED

UDI Request (IVDR) EUDAMED

UDI Request (MDR) EUDAMED

FDA - GUIDID

UDI Request

FDA

NMPA - CGUIDID

UDI Request

NMPA

### Maintain Common Device Data 04401587000203

**Issuing Agency:** GS1  
**UDI-DI:** 04401587000203

**DEVELOPER DATA** | **DIRECT MARKING** | **ADDITIONAL IDENTIFIERS** | **CHARACTERISTICS** | **PACKAGES** | **SUBMISSION STATUS**

**DEVELOPER DATA**

**Label:** 8TD7613336  
**Device Count:** 1  
**Unit of Use DI Number:**  
**Common Website:** www.p36labs.com

**Catalog Number:** GS1  
**Version or Model:**  
**GMDN:**  
**Production Identifier:**  
**Contact Mail:** info@projekraum36.de  
**Contact Phone:** 06621 7954500

**DIRECT MARKING**

**Device Subject to Direct Marking:** No  
**Direct Marking DI Number:**  
**Direct Marking DI different from Primary DI:** No

**ADDITIONAL IDENTIFIERS**

**Previous DI Number:**  
**Issuing Agency:**  
**Secondary DI Number:**  
**Issuing Agency:**  
**DI Number:**

**CHARACTERISTICS**

**Single use:** n/a  
**Over the Counter:** n/a  
**Contains Latex:** n/a  
**Not made with natural rubber latex:** n/a

**Validation List:**

- Version or Model
- Production Identifier
- Single use
- Contains Latex
- Not made with natural rubber latex
- Packaged as Sterile
- Requires sterilization prior use

**Buttons:** Save, Validate, Submit, Protokoll einblenden





# Let's talk!



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