GS1 Germany

The Global Language of Business

# Meeting UDI-requirements - Lessons Learnt and Customer Perspective

## LSA2018

Sylvia Reingardt, Senior Sector Manager Healthcare, GS1 Germany

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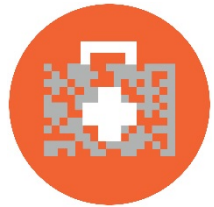

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# Are you ready for UDI?

- The United States Food and Drug Administration (FDA), the European Commission and other regulators have made **patient safety a strategic priority** by developing legislation for Unique Device Identification (UDI)

- UDI is expected to improve **patient safety** and **healthcare business processes**


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# GS1 role as UDI assigning entity

GS1 – as well as HIBCC and ICCBBA – is listed as “**UDI assigning entities**” until the EU Commission potentially designates others

- GS1 is one of the UDI assigning entity in the IMDRF Guidance
- GS1 was the first accredited UDI issuing agency by the US FDA


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# Facts & figures

- Private-sector, not-for-profit company based in Cologne, Germany
- 1974: Founded as the "Centrale for Coorganisation" (CCG)
- 2005: Renamed GS1 Germany
- Managing Director: Thomas Fell
- About 56,000 customers in 2017
- Over 180 employees, including ownership interests and subsidiaries over 400 employees
- Partner: EHI Retail Institute and the German Brands Association (Markenverband)
- Core product: The barcode and other globally applicable identification, communication and process standards


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# The Global GS1 Network

## International, non-overlapping and industry-independent

- 150 out of more than 190 countries around the world use GS1 standards
- over 1 million companies in the GS1 system
- 112 member organisations (MO)
- GS1 Germany is the second-largest MO
- Global Office based in: Brussels
- International networking: GS1 in Europe, Consumer Goods Forum, Global Standards Management Process


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# The hidden champion

## Everyone is familiar with it.

- The GS1 barcode can be found on nearly every retail product.
- 5 billion product identification scans are performed each day around the world.
- The barcode is one example of how GS1 standards and solutions are paving the way to the digital, globalised world.


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# Uniquely product information

Data Carrier **EAN-13**
(linear)

**GS1** France (30-37)

**Manufacturer**

**Product**

**Check Digit**

**GTIN:** 31 13910 31301 0


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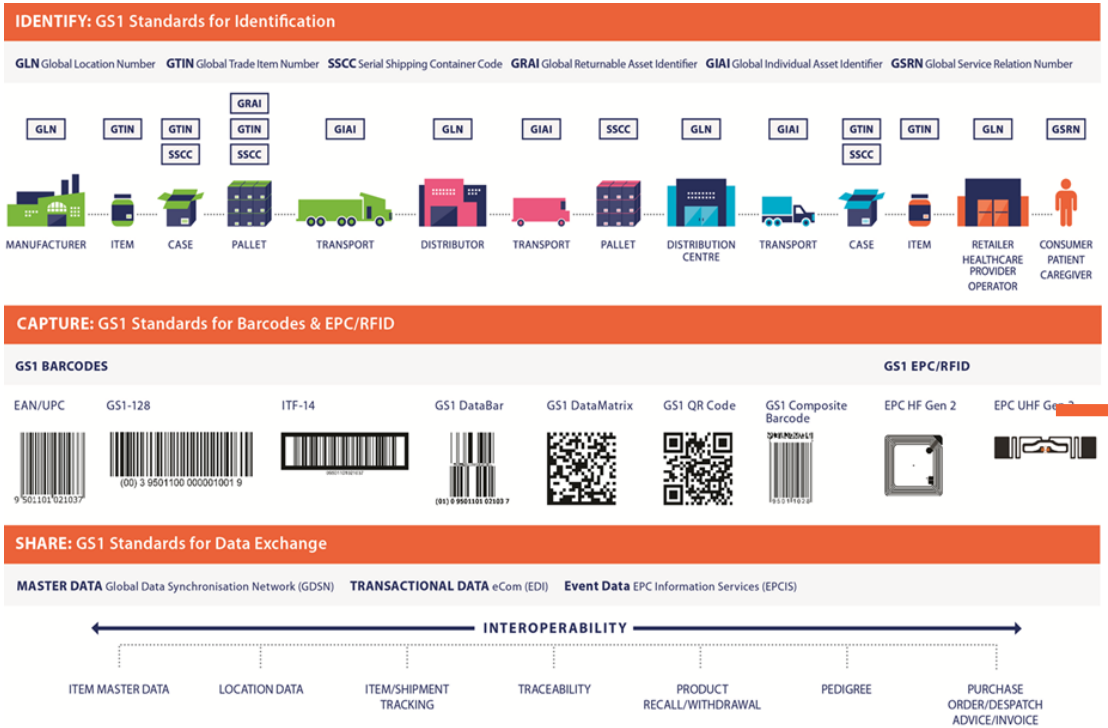
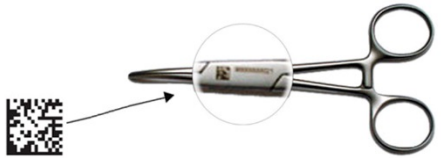
# The GS1 System





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# UDI system in EU

- Production of a UDI made of a DI and a PI
- Application of the UDI on the label or the package of the device. The UDI carrier shall be placed on the label and on all higher levels of packaging (not incl. shipping containers)
- Storage of the UDI by the economic operators, **the health institutions and the healthcare professionals**
- Establishment of a UDI database


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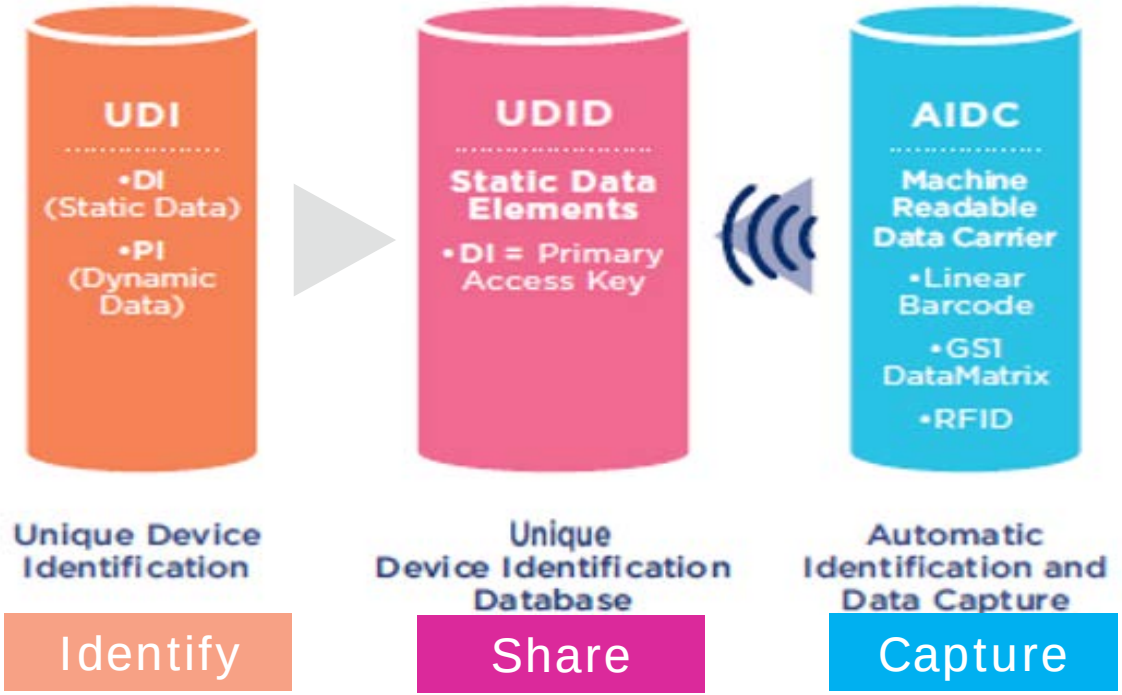
# UDI system at a glance





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# UDI in GS1 terms

| | |
|---|---|
| **UDI**<br>Unique Device Identification | **GS1 standards**<br>Product Identification |
| **DI**<br>Device Identifier (DI) | **GTIN**<br>Global Trade Item Number |
| **PI**<br>Production Identifier (PI)<br>*if applicable* | **AI**<br>Application Identifier (AI)<br>• Expiration date AI(17) - e.g. 141120<br>• Batch – lot AI(10) - e.g. 1234AB<br>• Serial number AI(21) - e.g. 12345XYZ |
| *Production Identifier data will vary by medical device type and manufacturer current practice.* | |
| **DI + PI = UDI** | **GTIN or GTIN + AI(s) = UDI** |


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# US vs EU UDI Differences

- Responsibility: US Labeler vs EU Legal Manufacturer
- Single Use Devices packaging exception: EU limited to class I/IIa[/class A/B]
- Procedure packs* (a.k.a. kits) and Systems: EU individual devices must ALSO be UDI compliant – unless Single Use Devices or already exempted
- Configurable device*: EU UDI on separately distributed components
- IVD Kits: EU UDI for individually distributed reagents and articles
- Standardized date format (YYYY-MM-DD): EU not required

* = Similarity is that these products are covered by UDI both in the EU and the US. However, the requirements are different. Refer to the regulation for clarification.


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# US vs EU UDI Differences

- Software: EU label and software UDI must be identical
- Class I devices: EU needs both DI and PI
- Direct Marking UDI: EU UDI must be both AIDC and HRI
- Direct Mark: EU does NOT exempt devices that are only cleaned between different patient use and single patient use.
- “Existing inventory” exemption: EU does not have


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# Benefits of the system UDI

- More accurate reporting, reviewing and analyzing of **adverse event**
- Reducing **medical errors** by providing health care professionals access to information
- Enabling to **document device use** in electronic health records, clinical information systems, claim data sources and registries.
- A more robust **post market surveillance** system
- Manage **product recalls**
- Foundation for a **global, secure distribution chain**, helping to address counterfeiting and diversion and prepare for medical emergencies


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# Real-life examples
# Inventory management


**72%**
**reduction of waste**

## Bernhoven Hospital (Netherlands) [1]

Implemented GS1 standardised unique barcode identification on medical devices **used in the operating rooms**, such as implants, and internal database with all information about the availability and location of medical devices.

Total value of stock/inventory of medical devices in the hospital's financial statement €807,000:

- **Reduction of stock by 31 %**
- **Reduction in stock value by 23 %**
- **Reduction of waste by 72 %**

[1] GS1 Reference Book 2015-2016


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# Real-life examples
# Inventory management

**< 1 %**
**waste**

## Portsmouth Hospital NHS Trust (UK)[1]

In order to resolve the **challenge of managing products with 13 different types of barcodes**,
it implemented the use of GS1 standards (GTINs, batch and lot numbers, expiry date and, where needed, serialisation number) to identify all products at inner and outer packaging level.

- **20 % stock reduction**
- **< 1 % waste**

[1] Case Studies GS1 UK 2015


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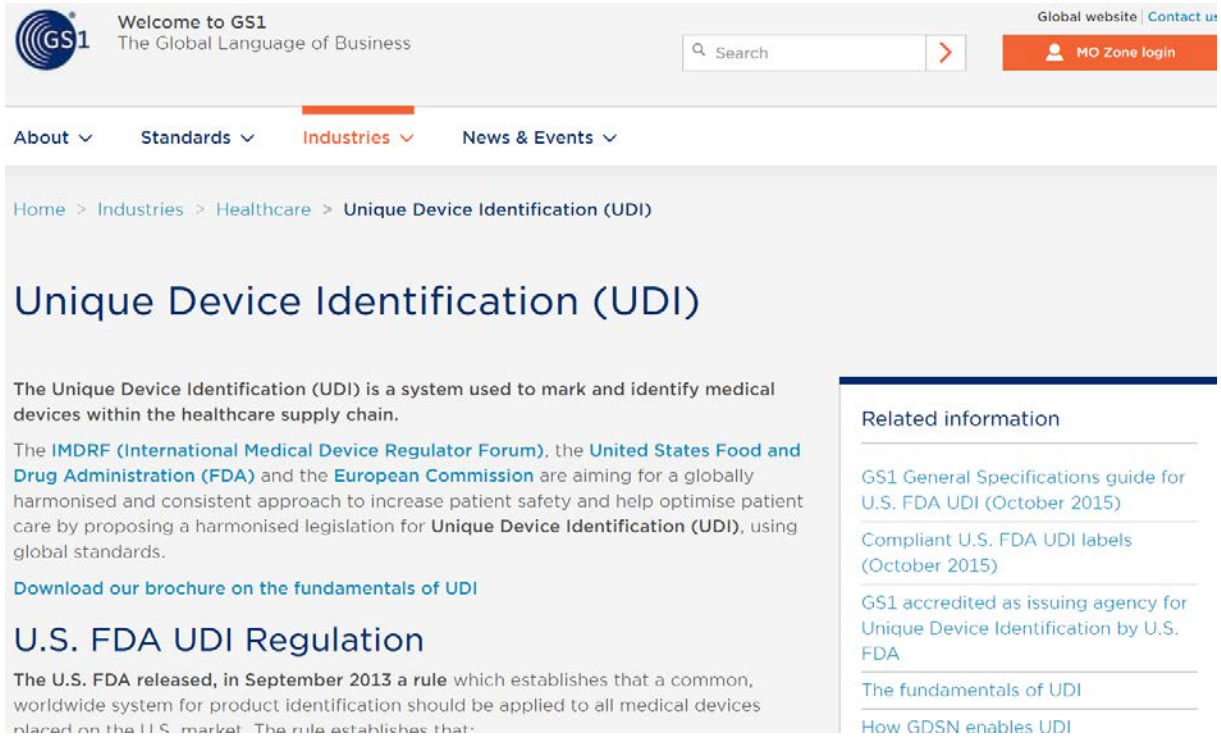
# http://www.gs1.org/healthcare/udi





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# Ultimately, it’s all about…

# PATIENT SAFETY!


**Global standards enable patient safety worldwide**


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# Questions?

**Sylvia Reingardt**

Senior Branchenmanagerin Gesundheitswesen

GS1 Germany

Maarweg 133

50825 Köln

**T** +49 (0)221 94714 438

**F** +49 (0)221 94714 7438

**M** +49 (0)175 1826895

**E** reingardt@gs1-germany.de

**www.gs1-germany.de**



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