

Implementing the UDI system in a SME environment

LINET spol. s r.o.
GS1 registered since 2010
UDI user since 2016

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LINET Group SE



Hospital equipment



Nursing home equipment



Gynecological practises

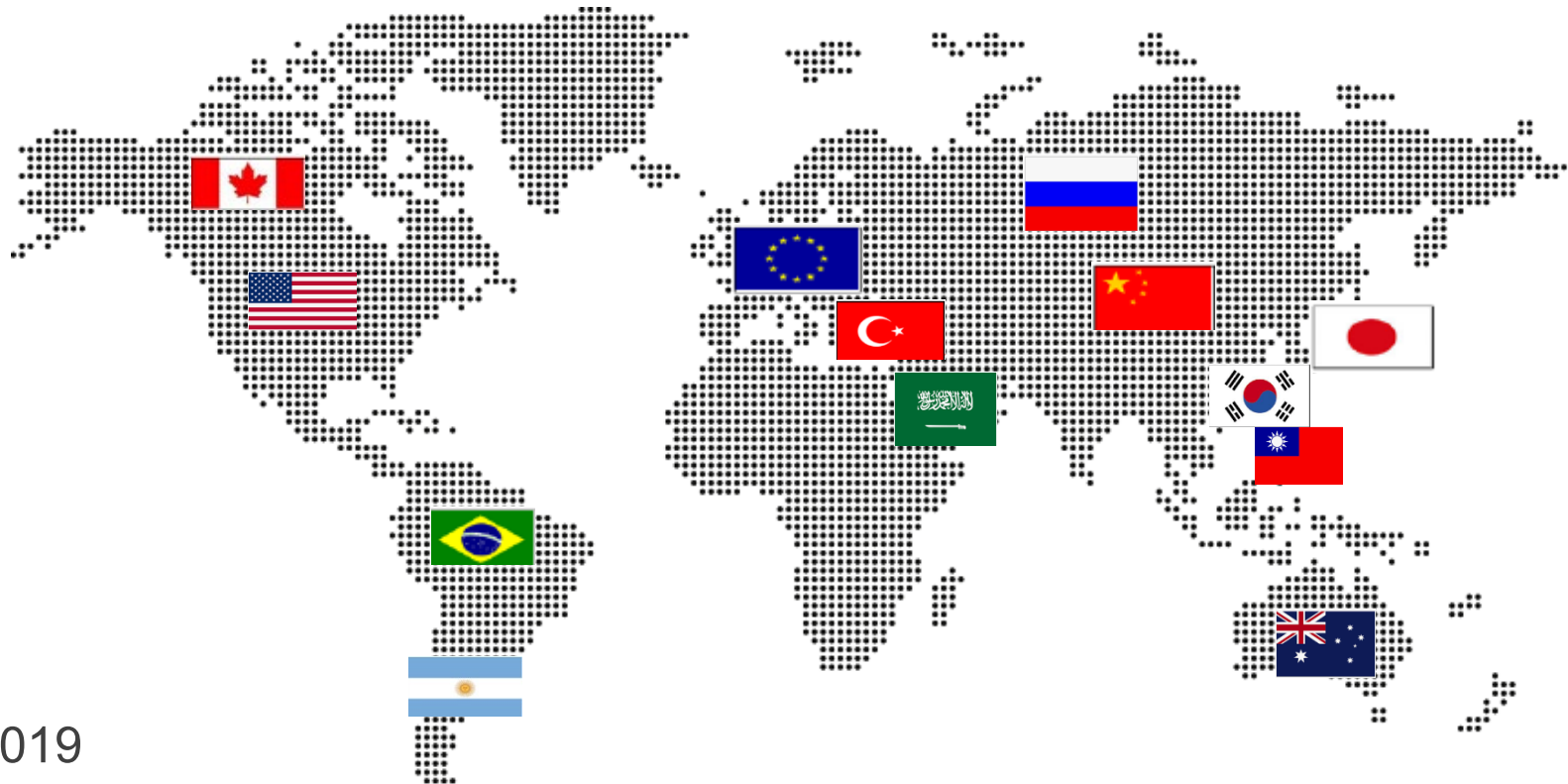


Goal

- Answer the questions:
 - What is expected scope of UDI system implementation?
 - What should be considered?
 - Who should be involved?
 - When to start?

„Too many companies have waited for the last minute to take action toward UDI compliance“ Beth Gibson, GS1 US, July 2016

UDI worldwide harmonization



2019

UDI history in Linet

- ✓ 2010
 - Special label with GTIN based on customer request only
 - Start of cooperation with GS1
- ✓ 2014
 - First contact with UDI FDA regulation
 - No further action
- ✓ 2015
 - Request of public hospital in Sweden: „Unique Device Identifier (UDI) for each medical device “
- ✓ 2016
 - UDI required for devices sold in USA (class II)
 - Decision to implement UDI for all products as preparation for EU MDR 2017/745

Technical label evolution


08/2015


1D bar code
GS1-128


2D bar code
GS1 Datamatrix

DI (Device Identifier) / GTIN (Global Trade Item Number)

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REF 1GE5yyyy-yy (PRODUCT NAME)	ORDER NO.: xx/xxxx/xx	<div style="border: 2px solid red; padding: 5px;"> (01)08592654120521 (11)160906 (21)20160063476 </div>	
SN XXXXXXXXXXXX	yyyy-mm-dd CFG: xxxxxxxx		

 =250 kg
  =185 kg
  =248 kg
 V_{in}:230V~, 50/60Hz
 P_n:370VA IPX4
 INT.:max. 2min ON/18min OFF


 CE 1014

GTIN

DATE

Serial Number

PI (Production Identifier)

What is behind? PROJECT!

- Goal: Establish ongoing UDI PROCESS in compliance with UDI rules and as part of existing QMS



Why project?

- UDI implementation is very complex task
- More than two departments involved

Based on:

- / Regulatory review and understanding of UDI requirements
- / Preliminary GAP analysis
- / Risk management/SWOT analysis
- / Consultations with external party

Strategic decisions

Issuing agency selection – strategic partner

✓ **GS1, HIBCC, ICCBBA** or ???

- Is a agency accredited by national authority/EC?
- Is the agency capable to be strategic partner?
- Do you already use existing codes from one of the existing agencies? If yes, what is your experience with the agency?
- Are your products sold internationally?
- How many DI's will you need?
- What is an expectation of your customers?



Strategic decisions

- ／ Type of implementation
 1. Do-it-yourself Implementation
 2. Limited Partner Implementation
 3. Full-On Outsource Implementation

- Do you have sufficient resources?



Strategic decisions

➤ Types of submission to UDID's

1. Manually

➤ UDID Web interface

2. Automatically

➤ Internal Software

➤ Hosted Software (Software as a Service)

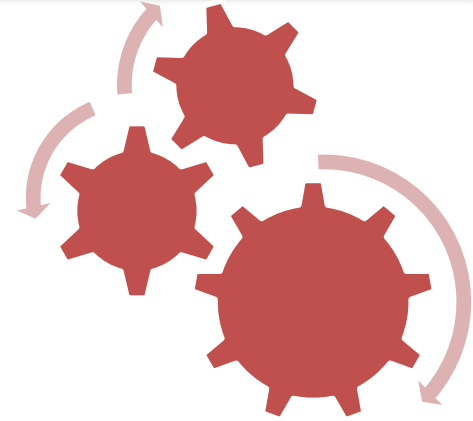
➤ Outsourced Service

- / How many DI's you have?
- / Are your products sold internationally?
- / How many UDID you have to fill ?



UDI process as part of QMS

- UDI process is NOT stand-alone process
- / Management commitment
- / Risk based approach
- / Operating procedure incl. responsibilities and authorities
- / Supplier controls – Issuing agency evaluation
- / Software/Process validation
- / Bar codes acceptance activities
- / ...



Who should be involved - Project team

Regulatory Affairs

Regulatory requirements
Data submissions

IT

ERP system connection
SW validation
Printers, scanners

RnD

Drawings
Labels stability, IFU

Production

Equipments, Labels printing,
Work instructions



**UDI
compliance**

Quality Assurance

QMS, Process risk evaluation
Internal audit, Process change
evaluation

Product Management/Marketing

Label size, UDI label placement on device

Purchasing

Suppliers controls, purchase of
equipment,
Contract manufacturers

Quality Control

Production acceptance activities
Legibility of the label

HR

People, training
Responsibility/authority

Main tasks

One-time:

- / Planning and administration and the costs to integrate the UDI into existing information systems
- / Installing, testing, and validate barcode printing software
- / Training employees
- / Redesigning labels of devices to incorporate the barcode and date format
- / Purchasing and installing equipment needed to print and verify the UDI on labels
- / Recordkeeping and reporting requirements
- / Direct marking of certain devices

Ongoing:

- / Labor, operating, and maintenance associated with equipment for printing operations
- / Labor related to software maintenance and training needed to maintain the UDI information system

Challenges

Internal

- Data management
- Communication
- Costs

External

- More than one UDI Database (National UDID)
- National deviations – e.g. Basic UDI-DI for EU

Summary

- UDI system is NOT only bar code on the label and data submission – it is ongoing process
- UDI compliance is complex task

- Take the action, do not underestimate UDI implementation

Thank you for your attention

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