GS1 Ireland

The Global Language of Business

Are you ready for UDI?

The Unique Device Identification Regulation means that the label of EVERY medical device, including all IVDs, must have a UDI.

Introduction

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. A single, global system of standards is fundamental to enable an efficient and effective implementation of UDI by all healthcare stakeholders worldwide.

GS1 standards for UDI

The GS1 System of Standards supports all stakeholders to efficiently and effectively meet UDI requirements by enabling interoperability within an organisation, between organisations and across borders. A single standard can ultimately accelerate implementation and increase compliance to the UDI regulations.

GS1 has over 110 member offices and more than 2,000 employees worldwide providing UDI implementation support to users in their own language combined with an understanding of local requirements.

Connect With Us

UDI training and advice

Interested in learning more about UDI implementation? We have a range of guides and resources that can be accessed via our website www.GS1ie.org/Healthcare/UDI.

- Do you require advice and staff training in preparation for compliance with US FDA UDI requirements?
- Do you understand how to correctly implement GS1 identification numbers on your production lines?
- Are you aware of the specifications for creating and printing barcode labels?

GS1 experts are on hand to provide you with the help needed. We offer both private, company specific tailored courses on your site or optionally you can choose to participate in one of our online webinars to learn about implementing GS1 identification standards such as GTINs and barcodes.

In December 2013, GS1 was accredited as an Issuing Agency by U.S. Food and Drug Administration (FDA) for Unique Device Identification (UDI) of Medical Devices to meet new patient safety, traceability and supply chain security regulations.

GS1 Ireland

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Overview of Unique Device Identification

Unique Device Identification in GS1 terms

UDI Unique Device Identification	**GS1 Standards** Product Identification
DI Device Identifier (DI)	**GTIN** Global Trade Item Number
PI Production Identifier (PI) (if applicable)	**AI** Application Identifier (AI) • Expiration Date AI(17) - e.g. 141120 • Lot/Batch AI(10) - e.g. 1234AB • 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**
GUDID (Global UDI Database) Data Elements linked to the DI (Device Identifier) element	**GS1 Certified Datapool** Attributes (product data) mapped to each GUDID data element

There are 3 elements to UDI

The Unique Identifier

UDI

- DI (Device Identifier) Static Data
- PI (Product Identifer) Dynamic Data

The Barcode

AIDC

Machine Readable Data Carrier
- Linear barcode
- GS1 DataMatrix
- RFID

Product Data

GUDID

Static Data Elements only

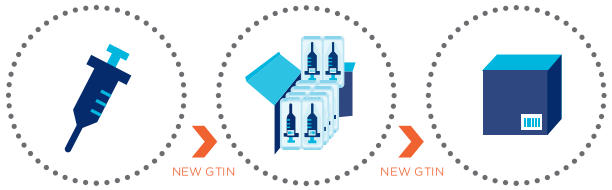
Primary Key= DI/GTIN

Examples of some of the data required:
(See FDA website for full list.)

Manufacturer Name	Controlled by Authorised Representatives
Address	Unit of Use
Brand Name	Sterility
Packaging Hierarchy	License/Marketing Authorisation
Nomenclature + Term	Clinical Warnings (Latex, MRI)
Device Model or Version	
Reference Number	
Clinical Size	

No batch or serial number information required for the UDI Database.

COMMON INDUSTRY PRACTICES



NOTE: GTINs below for illustration only

Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
5391234560008	5391234560015	5391234560022

WHEN THE UDI (DI) IS A GTIN

GTIN encoded in an EAN 13 barcode

5 391234 560008 >

GTIN encoded in a GS1-128 barcode

(01)05391234560008

GTIN encoded in a GS1 DataMatrix

(01) 05391234560008

WHEN UDI HAS DYNAMIC DATA

GTIN with Lot Number encoded in a GS1-128 barcode

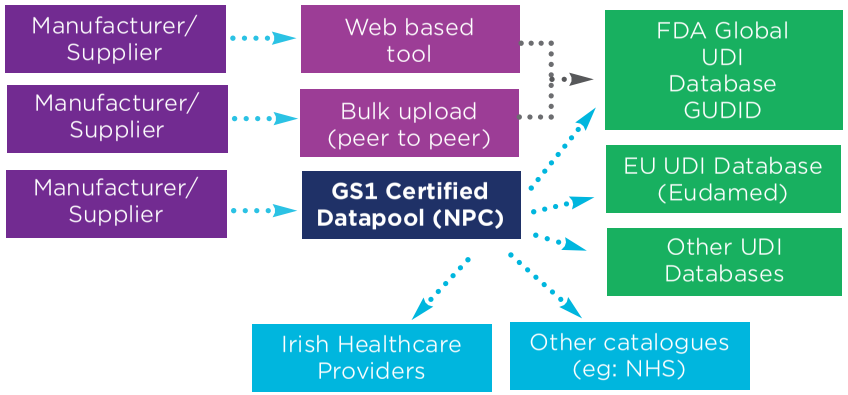
(01)05391234560008(10)987654321ABCD

GTIN Lot/Batch

GTIN with Batch, Expiry and Serial Number encoded in a GS1 DataMatrix

GTIN (01) 05391234560008
Expiry (17) 151231
Batch (10) 987654321ABCD
Serial (21) ABCD1234

US FDA REQUIREMENTS FOR PRODUCT DATA



There are different options for registering data in the US FDA Global UDI Database (GUDID).

GS1 certified data pools (called the NPC in Ireland) can register data on behalf of the manufacturers using the HL7 Structured Product Labeling (SPL) standard.

→ **Key Benefit**
Information uploaded once to the NPC can be shared to many locations (FDA, EU, Healthcare providers).

Note: It is expected that the EU requirements for UDI will be similar to those of the FDA with a compliance date of 2017 (phased approach based on risk class of medical device).