The Medical Device Manufacturer's Quick Reference Guide to

UDI

Unique Device Identification

Why is UDI required?

50,000 serious adverse events related to medical devices are estimated by the FDA to be reported each year

3,000 deaths are estimated to result

Medical device recalls have **doubled** in the last decade.

What is a UDI?

A unique numeric or alphanumeric code that includes:

01 A **device identifier (DI)**, which is specific to a device model

02 A **production identifier (PI)**, which includes the current production information for that specific device, such as lot or batch number, serial number, expiration date or a combination.

The FDA's 5 Main Requirements

01 The label of **every medical device must have a UDI**.

02 Assign a **globally unique, standardized identifier** to devices.

03 The UDI must appear **on the label in a human readable format**, plus in a format that can be **read by automatic identification and data capture (AIDC) technology**.

04 Directly **mark the UDI on the device itself** if the device is intended to be reused and reprocessed.

05 **Provide identifying information to FDA's GUDID database** for others to access and use.

Where do we **get the UDI number?**

Three Issuing Agencies (IA) currently accredited by the FDA assign the Device Identifier portion of the UDI.

What **date convention** should we use?

The UDI rule requires the ISO standard "YYYY-MM-DD" date format on the label.

What are the **penalties for noncompliance?**

Manufacturers will **not be able to sell their product in the US** if it is not labeled and uploaded to the FDA's GUDID. Potential enforcement actions include **seizure, injunction, civil and criminal penalties**.

Compliance Dates for UDI Requirements

Each of the items below are required to bear a UDI and the appropriate data must be submitted to the GUDID database.

By September 24:	Classification:
2015	Labels and packages of implantable, life-supporting, and life-sustaining devices
2016	Class III devices* required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself. Labels and packages of class II medical devices
2018	Class II devices* required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself. Labels and packages of class I medical devices and devices not classified into class I, class II, or class III
2020	Class I devices*, and devices* not classified into class I, class II, or class III, must bear UDI as a permanent marking on the device itself.

* If intended to be used more than once and to be reprocessed before each use

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Sources

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