What is UDI?

In 2013, the Food and Drug Administration (FDA) released a final rule establishing a unique device identification system designed to adequately identify devices through distribution and use. The final rule requires device labelers to include a unique device identifier (UDI) on device labels and packages,

Labelers are required to work with at least one accredited Issuing Agency and follow the Issuing Agency rules to build their UDI. All UDIs are to be issued under a system operated by an FDA-accredited issuing agency.

As part of the system, the device labelers are required to submit information to the FDA-administered Global Unique Device Identification Database (GUDID).

A "labeler" is any person who causes a label to be applied to a device, or who causes the label of a device to be modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label. The addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label is not a modification for the purposes of determining whether a person is a labeler. In most instances, the labeler would be the device manufacturer, but the labeler may be a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler.

Compliant Dates for UDI Requirements

Device	UDI/GUDID Compliance Date
Class I or unclassified device	September 24, 2020
Class II (Direct Marking Requirements)	September 24, 2018
Class II device	September 24, 2016
Implantable, life supporting, and life sustaining Device	September 24, 2015
Class III device and Class III Standalone software	September 24, 2014

Misbranding (Labeling Violations)

Section 502 of the Federal Food, Drug and Cosmetic Act (**FFDCA**) contains provisions on misbranding. A device's labeling misbrands the product if:

- **If its label does not bear required information as required (e.g. UDI)**
- **If its labeling proves false or misleading in any particular way**

FDA Judicial actions

When a firm violates the Federal Food, Drug and Cosmetic Act (FFDCA), U.S. FDA can perform judicial enforcement actions. E.g. *seizure, injunction, civil money penalties for radiation-emitting products, criminal prosecution.*

We can help

Focus 42 LLC, can help you to interpret and comply with all FDA UDI requirements. Click here to get your free proposal.