UDI/MDR REGULATION

Ensuring vision system compliance

The FDA requires every medical device labeler to include a Unique Device Identifier (UDI) on device labels and packages. If the device is multiple-use or implantable, the UDI code must be direct part marked (DPM) on the device. The labeler is almost always the manufacturer, but it can be a reprocessor or other entity as well.

What is UDI?

The UDI marks and identifies individual medical devices, making it possible to trace them through distribution and throughout their product lifecycle. It secures supply chains to prevent the counterfeiting of devices and manages safety recalls and adverse event reporting.

The UDI information must be displayed both in machine-readable form (1D or 2D code) and in human-readable form (alphanumerics).

Each UDI code has two parts:

- Device Identifier (DI): the model of the device
- Production Identifier (PI): production information about this specific unit, such as batch number, serial number, manufacturing date, expiration date, and distinct ID code

Manufacturers must submit device identifier information to the Global Unique Device Identification Database (GUDID) for each model they manufacture. The FDA requirement also assumes that manufacturers use a barcode verifier to confirm the code quality meets GS1 and HIBCC quality standards of a "C" grade or higher.

📄 Download Introduction to Barcode Verification

How are MDR requirements different?

The European Commission Medical Device Regulation (MDR) introduces a similar system in the EU. The UDI requirement applies to both new devices and those that have been on the market for years. Any company that has been marketing medical devices in the United States will be largely prepared for the EU version.

One significant difference is that, in addition to the UDI-DI and UDI-PI, the EU requires what is called a Basic UDI-DI for uploading to the European Databank on Medical Devices (EUDAMED). The Basic UDI-DI is used for a group of similar medical devices, like catheters, and is an alphanumeric code. The Basic UDI-DI is purely administrative and has no supply chain value.

In the EU UDI management responsibility lies with the manufacturer, not the labeler.

Direct UDI marking must be automatic identification and data capture (AIDC) and human-readable interpretation (HRI), not an FDA requirement.

What are the effects of UDI?

UDI mandates in the US and EU are requiring more integrated label management across supply chains. This is driving change by many manufacturers, as UDI improves adverse event reporting and supports faster recalls. The data generated by UDI is also increasing supply chain transparency and improving product quality.