

FDA Fact Sheets: Unique Device Identification (UDI)

To more effectively identify medical devices through their distribution and use, FDA requires devices be identified with a unique device identification (UDI) number.

A UDI is a unique numeric or alphanumeric code that is part of a device's labeling and includes a device identifier, which is specific to a device model, and a production identifier, which includes the production information for that specific device (lot, serial number or expiration date). Another component of the UDI system is an FDA-controlled database that includes a standard set of identifying elements for each UDI. This information is publicly available so that users of a medical device can easily look up the information.