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STANDARDS & GUIDANCE BRIEF · UNITED STATES · REGULATION

21 CFR Part 830

Unique Device Identification

DOCUMENT	QES-WP-109, Rev B	DATE	November 7, 2026
ISSUED BY	US Food and Drug Administration	PREPARED BY	Conner Davidson
EDITION	Current as published in the eCFR (labeling provisions in 21 CFR Part 801)	STATUS CHECKED	October 24, 2026
INDUSTRIES	Medical Devices	ONLINE	qesisbest.com/standard-21-cfr-830.html

IN FORCE Under the QMSR the UDI must also appear in the relevant quality records.

What It Covers

The UDI system: how device identifiers are issued, what goes on labels and packages, and the data submitted to FDA's Global Unique Device Identification Database (GUDID).

Who It Applies To

Labelers of devices marketed in the US, with exceptions set out in the rule.

Key Requirements

- A UDI on the label and each device package, in plain text and machine-readable form (21 CFR 801.20, 801.40).
- Direct marking for devices intended to be used more than once and reprocessed (21 CFR 801.45).
- Device identifier data submitted to and kept current in GUDID (§830.300 onward).
- Identifiers issued under an FDA-accredited issuing agency's system, such as GS1, HIBCC, or ICCBBA.

What an Auditor Asks to See

- GUDID records that match the label actually in use.
- The procedure for changing a device identifier when the device changes.
- UDI captured in production and distribution records.

Where Systems Fall Short

- GUDID entries left unchanged after a packaging or labeling change.
- New device identifiers not issued when a change requires one.

How QES helps. Reconciling the label, the GUDID record, and the change control process so they cannot drift apart. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. eCFR — 21 CFR Part 830 — www.ecfr.gov/current/title-21/part-830; eCFR — 21 CFR Part 801 — www.ecfr.gov/current/title-21/part-801.

A summary for orientation, prepared by Quality Excellence Services. It does not reproduce or replace the standard or regulation: read the official text, which governs. Not legal advice.