GLOBAL UDI
CONSULTANTS

LABELING SERVICES · PRINTER & SOFTWARE VALIDATION

Label printing done right. Validated. Verified.

Compliant UDI label design, label printer and BarTender setup, IQ/OQ/PQ validation packages, and label checks against your GUDID and EUDAMED records, all from one team.



Design · Print · Verify · Validate
Your label is part of the device.

IQ → OQ → PQ
Installed right. Works right. Prints right.

One source of truth
The label matches the GUDID / EUDAMED record.

Free 15–30 min video consultation · info@globaludi.com

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THE STAKES

Your label is part of the device.

A label that is wrong, unreadable, or out of sync with your device database is not a cosmetic problem. Regulators treat it as part of the device. A labeling error can mean misbranding, a recall, or an audit finding, and every one of those starts at the printer.

United States · FDA

- **21 CFR Part 801:** the device label must carry a UDI in both plain-text (human-readable) and AIDC (barcode / Data Matrix) form.
- **21 CFR Part 830:** device identifier data must be submitted to the FDA's GUDID, and it must match what is printed on the label.
- **QMSR (21 CFR Part 820, in effect since Feb 2, 2026):** brings ISO 13485:2016 in by reference, including validation of production software and processes.
- Under the FD&C Act, a device with false or misleading labeling is misbranded.

European Union · MDR / IVDR

- UDI carriers are required on labels, with Basic UDI-DI and UDI-DI data registered in EUDAMED.
- The EUDAMED registration deadline is **November 28, 2026**. Your label data and your EUDAMED records have to agree.
- A manufacturer needs an EUDAMED actor registration (SRN) before it can register any devices.

Where label risk really comes from

Unreadable barcodes

Worn print heads, the wrong print-quality mode, or media that doesn't suit the printer produce Data Matrix codes that fail at the scanner.

Data mismatches

The DI, model number, or device description on the label no longer matches GUDID or EUDAMED after a change.

Unvalidated systems

A printer and labeling software in production use with no IQ/OQ/PQ evidence is an easy audit finding.

Uncontrolled templates

Anyone can edit a template, with no version history, approvals, or locked fields.

Wrong production data

Lot, expiry, or serial numbers keyed in by hand, skipped, or duplicated across a batch.

No reconciliation

Printed, used, and voided labels are never counted, so loose labels end up on the wrong product.

THE FIX

You don't need a bigger team. You need a **defined, validated, verified labeling process**, and that is exactly what we build.

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PRINTING & LABELING SERVICES

Everything from the label template to the database record.

We cover the whole labeling chain: the data behind the UDI, the template that lays it out, the printer that puts it on media, and the validation evidence that proves the process works.

01

Compliant label design

UDI-compliant layouts with the DI and PI in human-readable and AIDC form, GS1 / HIBCC / ICCBBA syntax, symbols, and the regulatory content required for the US and EU markets.

02

Label template setup

Templates built in BarTender or similar tools: database-linked fields, serialized and incrementing data, Data Matrix and QR objects, locked layouts, and a controlled template library.

03

Label printer setup

Installing and configuring industrial label printers such as the Epson ColorWorks series: drivers, connectivity, media and print-quality settings, cut and stop modes, and admin lock settings.

04

IQ / OQ / PQ validation packages

Ready-to-execute protocols, test sheets, deviation logs, and a summary report for the label printer and the labeling software together.

05

Label checks vs. GUDID / EUDAMED

Field-by-field checks that the printed label (DI, brand, model, size, sterile and MRI status, and more) matches the data you have submitted or plan to submit.

06

UDI assignment

Structuring your Basic UDI-DI, UDI-DI, and packaging-level DIs, and choosing which production identifiers (lot, serial, expiry, manufacture date) go on each label.

07

Data collection & submission

As a registered third-party data collector and submitter, we gather, validate, and submit your device data to GUDID and EUDAMED.

08

Opening EUDAMED accounts

Actor registration and SRN, user access, and getting you ready to register devices ahead of the November 28, 2026 deadline.

ONE TEAM

Because we also submit your GUDID and EUDAMED data, your labels and your database records are built from **one source of truth.**

GLOBAL UDI
CONSULTANTS

NEXT STEP · FREE CONSULTATION

Book a free 15–30 minute video consultation call.

Our team will identify the gaps.

IN THE CALL WE'LL REVIEW

- Your current labels and UDI content
- Your printer and labeling software setup
- Your validation evidence (IQ/OQ/PQ)
- Your GUDID / EUDAMED readiness

YOU'LL LEAVE WITH

- A list of the gaps we found
- Recommended next steps
- A clear scope if you want our help
- No obligation

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Email us →

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Guides, templates, videos and the EUDAMED / GUDID readiness check.

Global UDI is a registered third-party GUDID & EUDAMED data collector and submitter.