GLOBAL UDI
CONSULTANTS

SUMMARY · LABEL PRINTING & VALIDATION

Label printing & UDI compliance: the summary.



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

8 services
From label template to database record

22 tests
Across IQ, OQ and PQ

Nov 28, 2026
EUDAMED registration deadline

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WHY LABELS MATTER

Your label is part of the device.

A label that is wrong, unreadable, or out of sync with your device database can mean misbranding, a recall, or an audit finding, and every one of those starts at the printer.

United States · FDA

- 21 CFR 801: UDI in plain-text and AIDC (barcode / Data Matrix) form
- 21 CFR 830: DI data goes to GUDID and must match the label
- QMSR (21 CFR 820, since Feb 2, 2026): ISO 13485:2016 incl. production software validation

European Union · MDR / IVDR

- UDI carriers on labels; Basic UDI-DI and UDI-DI in EUDAMED
- EUDAMED registration deadline: November 28, 2026
- Actor registration (SRN) needed before any device registration

SERVICES OVERVIEW

Everything from the label template to the database record.

01 **Compliant label design**

02 **Label template setup**

03 **Label printer setup**

04 **IQ / OQ / PQ validation packages**

05 **Label checks vs. GUDID / EUDAMED**

06 **UDI assignment**

07 **Data collection & submission**

08 **Opening EUDAMED accounts**

IQ / OQ / PQ at a glance

IQ · 7 tests

Is it installed correctly, per the manufacturer's specification?

OQ · 12 tests

Does every function work across its operating range?

PQ · 3 tests

Does it consistently produce conforming labels in production?

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OUR 5-STEP PROCESS

From "is this compliant?" to "released for use."

01

Assess

Gap assessment and a prioritized action list

02

Set up

Approved label designs, controlled templates, and a configured printer

03

Validate

Executed IQ/OQ/PQ, test sheets, logs, and the IOPQ summary report

04

Verify against GUDID / EUDAMED

Label-to-record verification and submissions ready to go

05

Hand off

Hand-off pack, operator guidance, and a revalidation trigger list

TOP BEST-PRACTICE TIPS

- Put the UDI in human-readable and AIDC form from the same data source
- Use your issuing agency's syntax (e.g. GS1 AIs) correctly
- Give each packaging level its own DI and quantity
- Scan every symbol and compare decoded data with the master record
- Reconcile printed, used, and voided labels on every run
- Link templates to a controlled data source, not hand-typed text
- Lock layouts; version-control templates
- Test serialization: no skipped or duplicate values
- Grade print quality with an ISO/IEC 15415 / 15416 verifier
- Revalidate after any change to printer, firmware, software, media, or template

COMMON MISTAKES WE CATCH BEFORE YOUR AUDITOR DOES

- ✕ **"It scans, so it's fine."** A scan is not print-quality grading.
- ✕ **Label ≠ GUDID / EUDAMED.** Data changes on one side only.
- ✕ **Half-validated system.** Qualify printer and software together.
- ✕ **Settings drift after PQ.** Unlocked settings quietly invalidate the PQ.
- ✕ **No reconciliation.** Leftover labels end up on the wrong lot.

FREE CALL

Book a free 15–30 minute video consultation call. Our team will identify the gaps.
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