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.

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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.**

HOW IQ / OQ / PQ WORKS

Installed right. Works right. Prints right. Every time.

Validation is done in three phases, each with its own protocol, acceptance criteria, and sign-off. Each phase must be completed and approved before the next one starts. The printer is released for medical-device labeling only after all three pass.

IQ
Installation Qualification
7 TESTS

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

WHAT WE VERIFY

- Equipment and component identification, checked against the packing list
- Power, surface, clearance, and facility checks (with a multimeter)
- Correct ink cartridges and maintenance box for the model
- Maintenance tasks added to your maintenance system
- Driver and BarTender installation, licensing, and connectivity
- Documentation under control (SOPs, manuals)
- Health, safety, and environment: temperature, humidity, guards, caution labels

OQ
Operational Qualification
12 TESTS

Does every function work across its operating range?

WHAT WE VERIFY

- USB, LAN, and Wi-Fi connectivity, including loss and recovery
- Touchscreen and panel functions, error messages
- Nozzle check, head cleaning, and maintenance functions
- Media loading, detection, and sensor calibration
- BarTender: Data Matrix and QR scan, serialization, batch counts, job cancel
- Cutter and stop modes, cut-position tolerance
- Print position, colour correction, admin lock and password
- Each print-speed and quality mode passes the label QC check

PQ
Performance Qualification
3 TESTS

Does it consistently produce conforming labels in production?

WHAT WE VERIFY

- Settings fixed and locked at the optimum confirmed in OQ
- Three consecutive production-representative batches per label type
- 100% content match against the master data record
- Every barcode / Data Matrix scans first time and decodes correctly
- No print-quality drift from the first label to the last
- Label adhesion and application on the real device
- 100% label reconciliation and traceability

What you receive

Protocols
IQ, OQ, and PQ with objectives, methods, and acceptance criteria

Test sheets
Label-by-label P/F sheets for print, legibility, smudging, scan, and reconciliation

Logs
Deviation, reconciliation, and attachment logs for traceability

Summary report
A combined IOPQ validation summary that supports release for use

Protocols are aligned with ISO 13485:2016, the QMSR, 21 CFR Part 11 (electronic records), ISO 14971 (risk management), and the GAMP 5 risk-based approach.

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BEHIND THE SCENES

1 printer. 3 protocols. 22 tests.

What a typical validation package covers for an Epson ColorWorks CW-C4000-class printer running BarTender, with example acceptance criteria from our protocols.

PHASE	TEST AREA	EXAMPLE ACCEPTANCE CRITERIA
IQ 1–3	**Identification · Facility & electrical · Consumables**	All components present and undamaged; dedicated grounded outlet; AC adapter output checked against the rating; ink and maintenance box part numbers correct for the model and within expiry.
IQ 4–6	**Maintenance · Software install & connectivity · Documentation**	Every maintenance task has a documented method and frequency. Driver and BarTender versions are recorded and licensing confirmed. Self-test print and BarTender test label are both legible. SOPs and manuals are under document control.
IQ 7	**Health, safety & environment**	Cutter guard and cover interlock work and caution labels are present. Temperature and humidity are within the manufacturer's printing range (tighter for barcode printing).
OQ 1–4	**Connectivity · Panel · Maintenance functions · Media handling**	The printer recovers from a connection loss without a restart. Locked settings are blocked for unauthorized users. The nozzle check prints fully. Sensor calibration finishes with no errors.
OQ 5	**Labeling software (BarTender)**	Data Matrix and QR codes print in the right position and size and decode correctly. Serial data increments correctly. Batch count matches the print queue. Cancelling mid-batch leaves no half-printed label. Templates save and reload intact.
OQ 6–10	**Cutter & stop modes · Utility & driver config · Print position · Colour · Security**	Cut position within tolerance. A settings backup restores correctly. Position adjustments are real and repeatable. Colour output is consistent. The default admin password is replaced with a site-controlled one.
OQ 11–12	**Variable data · Speed & quality modes · Optimization**	No skipped, duplicated, or corrupted values. Every quality mode passes the functional QC check (accurate, legible, no smudging, scannable). The optimum setting is chosen and recorded for PQ.
PQ 1	**Print quality, content & scan verification**	Three batches per label type at locked settings. Zero visible defects. 100% content match against master data. Every code scans first time with the correct decoded value.
PQ 2	**Adhesion & application**	Labels apply cleanly with no bubbles or lifting edges, still adhere after the dwell period, and stay legible and scannable.
PQ 3	**Reconciliation & traceability**	Labels printed equal labels required once voids are counted. Every void is recorded with its disposition. No loose labels at the end of a run.

Built-in deviation control

Every test ends with "Acceptance criteria met: YES / NO". Any NO is logged as a deviation and assessed for its impact on validation status before the summary report is signed.

Tailored to your setup

Label types, batch sizes, media, connection method, and colour pipeline are set to match how your site actually prints, not a generic template.

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HOW WE WORK WITH YOU

Five steps from "is this compliant?" to "released for use."

A clear, documented path with a defined output at every step, so your QA team always knows where the project stands.

01 Assess

We review your current labels, templates, printer, software, SOPs, and the GUDID / EUDAMED data you have or plan to submit. We find the gaps: missing UDI elements, unreadable symbols, uncontrolled templates, and missing validation evidence.

OUTPUT
Gap assessment and a prioritized action list

02 Set up

We design or correct label layouts, build database-linked templates in your labeling software, assign or confirm your UDI-DIs, and configure the printer's media, quality, cut, and security settings.

OUTPUT
Approved label designs, controlled templates, and a configured printer

03 Validate

We write and support execution of the IQ, OQ, and PQ protocols for the printer and software together, from installation checks through three-batch production runs, managing deviations along the way.

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

04 Verify against GUDID / EUDAMED

We compare printed labels field by field with your device records and, as your registered submitter, collect, correct, and submit that data so the label and the database say the same thing.

OUTPUT
Label-to-record verification and submissions ready to go

05 Hand off

We hand over everything your team needs to run it: template change control, a routine QC check, reconciliation, maintenance schedules, and triggers for revalidation.

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

START ANYWHERE

Some clients need only a printer validation package. Others need end-to-end labels plus GUDID and EUDAMED submission. **We scope the work to your gaps.**

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BEST PRACTICES FROM THE FIELD

The labeling checklist we use on every project.

Label content & UDI

- Put the UDI in both human-readable and AIDC form, generated from the same data source
- Use your issuing agency's syntax (e.g. GS1 Application Identifiers) correctly
- Include only the production identifiers you actually control (lot, serial, expiry, manufacture date)
- Give each packaging level its own DI and quantity

Templates & software

- Link templates to a controlled data source, not hand-typed text
- Lock layouts; restrict who can edit, approve, and print
- Version-control templates and keep an approved master library
- Test serialization: no skipped or duplicate values, and batch counts that match the queue

Printer & media

- Use only the specified consumables and media qualified for the printer
- Keep the printer in its rated temperature and humidity range, which is tighter for barcodes
- Schedule nozzle checks and head cleaning; enable auto nozzle check
- Replace the default admin password and lock the panel settings

Verification & control

- Scan every symbol and compare the decoded data with the master record
- Use an ISO/IEC 15415 / 15416 verifier for print-quality grading; a plain scanner only tells you whether a code reads
- Reconcile printed, used, and voided labels on every run
- Revalidate after any change to printer, firmware, software version, media, or template

5 common labeling mistakes we catch before your auditor does

- ✕ **"It scans, so it's fine."** Passing a scan is not the same as print-quality grading, and marginal codes fail in the field.
- ✕ **Label and GUDID / EUDAMED disagree.** Device descriptions, model numbers, or DIs change on one side but not the other.
- ✕ **Validating the printer but not the software** (or the other way round). They work as one system and should be qualified together.
- ✕ **Settings drift after PQ.** Unlocked print-quality and speed settings get changed and quietly invalidate the PQ.
- ✕ **No reconciliation.** Leftover pre-printed labels from an old run get applied to the wrong lot.

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WHY GLOBAL UDI

Labeling experts who also own your UDI data.

Most vendors stop at the printer. Others only handle database submissions. We connect the two, so what's printed on your label and what's on file with regulators always match.

Registered GUDID & EUDAMED data collectors and submitters

We handle the device data behind your UDI, from collection and validation through submission, so your labels are built on records that are correct.

Ready-to-execute validation packages

Detailed IQ/OQ/PQ protocols with clear acceptance criteria, test sheets, and logs, written around your printer's own technical reference guide.

Hands-on with printers and software

Practical experience with industrial colour label printers like the Epson ColorWorks series and labeling software like BarTender.

US, EU and Australia in one plan

21 CFR Parts 801 and 830, the QMSR / ISO 13485, EU MDR / IVDR UDI requirements and TGA AusUDID, handled together with no duplicated effort.

Who we help

New label printer

You bought a printer and need it installed, configured, and validated before you use it on product.

EUDAMED-bound

You need an EUDAMED account, device registration, and labels that match, before Nov 28, 2026.

Audit-ready

You have labels in production, but your template control, verification, or validation evidence has gaps.

8	22	5	Nov 28
labeling services, label to database	IQ / OQ / PQ tests	steps to "released for use"	2026 · EUDAMED deadline

START NOW

Accounts, device data, and labels take time to line up. **Book a free call →**
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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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Guides, templates, videos and the EUDAMED / GUDID readiness check.

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