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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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

Book your free call

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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.

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Mon–Fri, 8 AM – 6 PM CT