ISO 13485 Quality Kit — Free Sample

Free sample — 2 complete SOPs from the full kit. Try it before you buy.

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Please note: These templates help a small manufacturer build its quality system. They are not a guarantee of ISO 13485 certification, and the buyer should get a quality consultant for certification.

SOP 01 — Handling a customer complaint

Purpose: To log, investigate, and answer every complaint about the Medivance instrument tray, so no complaint is lost and no faulty tray stays in use. **Scope:** Every complaint about the tray, by phone, email, letter, or through a distributor — damage, rust, a lid that will not close, sharp edges, missing parts, or a tray that came back dirty after cleaning. **Who does it:** The Office Manager logs the complaint and sends the first reply. The Quality Lead investigates it. The Managing Director signs off complaints involving injury, patient risk, or a refund or replacement.

Steps

1. Log the complaint the same working day in the Complaint Log, with the next number (for example, C-2026-014).
2. Record the customer's name, date, contact method, tray model and batch number, how many trays are affected, and what happened, in the customer's own words where possible.
3. Ask for photos and the batch number from the tray label, if not already sent. Keep the photos with the record.
4. Reply within 2 working days, giving the complaint number and saying when we will update them again.
5. If the tray is returned, inspect it. If not, check the photos and the batch record: who made it, what steel was used, and when it was polished and inspected.
6. Write the cause in plain words — for example, "weld bead not polished smooth on batch 214" — not just "manufacturing fault".
7. Decide what to do: replace, repair, or refund the tray, or explain that no fault was found and why. Tell the customer and do it within 10 working days.
8. Search the Complaint Log for the same fault, such as "rust" or "lid". If it has happened before, tell the Quality Lead. It may need a CAPA — a corrective and preventive action, a formal fix that stops the problem coming back (see SOP 06).

9. If the complaint involves an injury or a tray that could have harmed someone, tell the Quality Lead at once. It may need reporting to the regulator (see SOP 03).
10. Close the complaint only when the customer knows the outcome, any replacement or refund has been sent, and the Quality Lead has signed the record.

Quality check: Once a month, the Quality Lead checks the Complaint Log against the email inbox and phone message book. Any complaint open over 10 working days is listed for review. **If it goes wrong:** If a complaint is missed, log it as soon as it is found, note the delay, and tell the customer. If a customer is unhappy with the answer, the Managing Director reviews the case and phones them. **Records:** Complaint Log entry, emails and photos, investigation notes, batch record copy, and signed closure note. Keep for at least 5 years.

SOP 02 — Complaint trend review

Purpose: To spot patterns in complaints before they become a serious problem, so Medivance fixes a repeating fault instead of answering the same complaint again and again. **Scope:** All complaints from the last 3 months, and all complaints from the last 12 months once a year. Every tray model and batch. **Who does it:** The Quality Lead prepares the review. The Managing Director and the Production Lead attend the meeting and agree the actions.

Steps

1. At the end of each month, count that month's complaints by type — rust spots, lid not closing, sharp edge, missing divider, dirty on arrival.
2. Count complaints by batch, and work out the complaint rate: complaints divided by trays sold. Write it plainly, for example, "3 complaints out of 400 trays — 0.75%".
3. Compare this month with the last 3 months. Mark any type up by 2 or more, any batch with 2 or more complaints, and any new type of complaint.
4. Read the details of the complaints that stand out. Look for a shared cause, such as the same steel supplier, the same polishing step, or trays made in the same week.
5. Once every 3 months, hold a 30-minute review meeting with the Managing Director and the Production Lead. The Quality Lead brings the counts, the rates, and a one-page summary.
6. For each pattern, decide: do nothing, watch it for another month, or start a CAPA — a corrective and preventive action, a formal fix that stops the problem coming back (see SOP 06). Write the decision and the reason.
7. If a pattern points to a safety risk — sharp edges that could cut a user, or trays that cannot be cleaned properly — treat it as urgent. Start a CAPA the same day and check whether the regulator needs telling (see SOP 03).
8. Once a year, in January, do a full 12-month review. Compare the year with the year before, list the top 3 complaint types, and set a target, such as "cut rust complaints by half".
9. Write a short Trend Review Report: counts, rates, patterns, decisions, and who does what by when. Everyone at the meeting signs it.

10. File the report with the Complaint Log. Add any new CAPA to the CAPA Log, and check at the next monthly review whether the action worked.

Quality check: The Managing Director checks that the monthly count was done on time and the quarterly meeting happened. A missed month is caught up the following week. **If it goes wrong:** If complaints about one fault jump suddenly — for example, 5 in one week — do not wait for the quarterly meeting. The Quality Lead tells the Managing Director the same day, and the team decides whether to pause sales of that batch. **Records:** Monthly counts, quarterly Trend Review Reports, annual review report, and meeting notes. Keep for at least 5 years.