

Medical device complaint and CAPA record

One record per complaint about a medical device, from the day it arrives to closure: who complained and how to reach them, which device, UDI, lot and serial number, what happened, whether it is a complaint at all, whether it is investigated (and the reason when it is not), whether it has to be reported and to whom, the link to a nonconformance or CAPA record, the cause, the actions, the effectiveness check, the reply and the sign-off. It is laid out for a manufacturer selling in the United States, the EU or both. Section 6 prints only the reporting periods stated in the texts read on 21 October 2026, each with its source: whether an event is reportable is a decision made under your own procedures, and the form records it without making it. This is not a validated form; FDA, competent authorities, notified bodies and ISO have not reviewed or accepted it, and nothing here is legal or regulatory advice. The section titles, tick boxes and wording are ours, to change.

Text (read 21 October 2026)	What it asks of a complaint record	Sections
21 CFR 820.35(a), Quality Management System Regulation (US, in force since 2 February 2026)	Records of the review, evaluation and investigation of complaints about a possible failure of a device, its labeling or packaging to meet a specification, and a recorded justification when a similar complaint was already investigated. For complaints that are reportable under Part 803, must be investigated, or were investigated anyway: device name, date received, UDI or UPC and other identification, the complainant's name, address and phone number, nature and details, any correction or corrective action, any reply.	1 to 5, 8, 10
ISO 13485:2016 (clause numbers and titles only)	4.2.5 Control of records; 8.2.2 Complaint handling; 8.2.3 Reporting to regulatory authorities; 8.5.2 (corrective action). Section 820.35 adds to clauses 4.2.5 and 8.2.2, and 820.10(b)(3) ties 8.2.3 to Part 803.	All
21 CFR Parts 803 and 806 (US)	Medical device reports, and an MDR event file holding what was used to decide whether an event was reportable and the decision; reports or records of corrections and removals. Periods in section 6.	6, 11
Regulation (EU) 2017/745, Articles 87 to 89	Reports of serious incidents and field safety corrective actions to the competent authorities, trend reporting, the manufacturer's investigation and final report. Periods in section 6.	2, 6, 8

1 Complaint intake

Complaint number	Date received by anyone in the organisation	Received by (name, role)	Date entered in the complaint file
How received ☐ Phone ☐ Email ☐ Letter ☐ Web form ☐ Sales or service visit ☐ Distributor or importer ☐ Returned device ☐ FDA or a competent authority ☐ Literature or social media ☐ Other			
Complainant name	Address	Phone and email	
Complainant is ☐ Patient or lay user ☐ Healthcare professional ☐ User facility ☐ Distributor or importer ☐ Own employee ☐ Other			
Country where the event happened	Date of the event, if known	Initial reporter, if not the complainant (for example the clinician who told the distributor)	

2 Device identification

Device name (brand name and common name)	Model or catalogue number	Software or firmware version	
UDI (device identifier and production identifiers) or UPC, and any other identification	Lot or batch	Serial number	Manufacture and expiry dates
Markets where this device or lot was distributed ☐ United States ☐ EU / EEA ☐ United Kingdom ☐ Other (name)		Device class (US, EU)	Quantity involved
Device or sample ☐ Returned ☐ Requested ☐ Still with the user ☐ Discarded ☐ Not applicable		Date returned and where it is held	
Held unaltered until evaluated? Article 89(1) of the EU MDR: after a serious incident is reported, no investigation that alters the device or a batch sample in a way that may affect later evaluation of the cause before the competent authorities are informed ☐ Yes ☐ No (say why under section 5) ☐ Not applicable			

3 What happened

Nature and details of the complaint, as reported (the complainant's words where possible), with any error codes, readings or photos and where they are filed		
Person involved ☐ Patient ☐ User ☐ No one ☐ Unknown	Device in use on a patient at the time? ☐ Yes ☐ No ☐ Unknown	Use error suspected? ☐ Yes ☐ No ☐ Unknown
Outcome reported ☐ Death ☐ Serious injury or serious deterioration of health ☐ Medical or surgical intervention ☐ Injury, not serious ☐ No injury ☐ Unknown		
Immediate actions (stock hold, quarantine, interim contact with the complainant), who and when		

4 Is it a complaint?

Does the communication allege a deficiency in the identity, quality, durability, reliability, safety, effectiveness or performance of a device after its release for distribution? (How FDA's reporting page describes a complaint; under the QMSR the ISO 13485 definitions apply (21 CFR 820.3), as your procedure sets them out.) ☐ Yes: complaint ☐ No: enquiry, service request or feedback (say where it went)	
Possible failure of the device, its labeling or its packaging to meet a specification? ☐ Yes ☐ No ☐ Not yet known	If not a complaint: reason, by whom, date
Could it be a reportable event in any market? If yes or unsure, start section 6 now ☐ Yes ☐ No ☐ Unsure	Date of awareness used in section 6 (21 CFR 803.3 says when a manufacturer is considered aware)

5 Investigation decision and investigation

Decision ☐ Investigate ☐ Not investigated: a similar complaint was already investigated ☐ Not investigated: other reason under our procedure		
Earlier complaint or CAPA number whose investigation covers this one	Justification for not investigating (why the earlier investigation applies to this device, lot and failure)	Decided by, date
Device evaluation and test results (returned device, retained samples)		
Device history or batch record review for this lot	Labeling and instructions for use review	
Similar complaints found (number, period and files searched)	Risk management file reviewed (reference, hazard already covered?)	
Findings and conclusion: is the complaint confirmed, and what failed		Investigated by, date

6 Reportability by market (decide for every market where the device is made available)

Date of awareness (day 0)	Decided by (name, role); for a US decision not to report under 21 CFR 803.20(c)(2), the person qualified to make a medical judgment	Reviewed by, date
---------------------------	---	-------------------

Market and report	Question the text asks	Period the text states	Yes / No / Unsure	Due date	Sent on, report no.
US: MDR, death or serious injury (21 CFR 803.50(a)(1))	Does information reasonably suggest the device may have caused or contributed to a death or serious injury?	No later than 30 calendar days after becoming aware			
US: MDR, malfunction (803.50(a)(2))	Did it malfunction, and would this or a similar device be likely to cause or contribute to a death or serious injury if it recurred?	No later than 30 calendar days after becoming aware			
US: 5-day report (803.53)	Does the event need remedial action to prevent an unreasonable risk of substantial harm to public health, or has FDA asked in writing?	No later than 5 work days after becoming aware			
US: supplemental report (803.56)	Has information arrived that the first report did not include?	Within 30 calendar days of receiving it			
US: correction or removal (806.10)	Was a correction or removal started to reduce a risk to health, or to remedy a violation that may present one?	Within 10 working days of starting it; if not reportable, a record under 806.20			
EU: serious incident (MDR Art. 87(1)(a), 87(3))	Did the incident directly or indirectly lead, or might it have led or might it lead, to death, a serious deterioration of health or a serious public health threat?	Immediately once a causal link is established or reasonably possible; not later than 15 days after awareness			
EU: death or unanticipated serious deterioration (87(5))	Is the serious incident one of these?	Not later than 10 days after awareness			
EU: serious public health threat (87(4))	Is there a serious public health threat?	Immediately; not later than 2 days after awareness of the threat			
EU: field safety corrective action (87(1)(b), 87(8))	Is a field safety corrective action planned?	Before it is undertaken, without undue delay (except in urgent cases)			
EU: final report (89(5))	Is the investigation of the reported serious incident complete?	Article 89 states no period			
Other market (name the rule)					

Unsure? The EU MDR says to report within the period anyway (Art. 87(7)), and an incomplete first report may be followed by a complete one (Art. 87(6)). Expected side-effects that are documented in the product information, quantified in the technical documentation and covered by trend reporting are not reported one by one (Art. 87(1)(a), Art. 88). **Not reporting in the US?** Keep the information the qualified person used (803.20(c)(2)) and the deliberation and decision in the MDR event file (803.18(b)(1)(i)). Importers and user facilities have other periods (803.10); this form is for the manufacturer. Periods of other countries come from your own procedure: the form states none.

Rationale for each No or Unsure above, with the information used (or where it is filed)

7 CAPA link and root cause

CAPA ☐ Opened ☐ Linked to an existing CAPA ☐ Not needed	CAPA number	NCR number	Reason when no CAPA is opened or linked
Root cause, in one or two sentences (the why-chain and its evidence sit in the NCR or CAPA record)			
Cause category ☐ Design ☐ Manufacturing ☐ Supplier ☐ Labeling or instructions ☐ Packaging ☐ Use error or use environment ☐ Not confirmed			
Risk management file updated? ☐ Yes ☐ No change needed	Reference, or why no change		

8 Corrections and corrective actions

No.	Action	Type (correction, corrective action, field action, labeling or IFU change, design change, supplier action)	Owner	Due	Done	Evidence reference

In the EU, a field action taken to prevent or reduce the risk of a serious incident is a field safety corrective action (Art. 2(68)): it is reported (Art. 87(1)(b)) and users are told through a field safety notice that identifies the device, including its UDIs (Art. 89(8)). In the US, check a correction or removal against 21 CFR 806.10 in section 6.

9 Effectiveness check

Result that will count as effective, written before the check		Method and data (complaint trend, tests, audits)	
Result found		Effective? ☐ Yes ☐ No: CAPA reopened	Checked by, date

10 Reply to the complainant

Date	By whom and how (phone, letter, email)	Summary of the reply
No reply sent: reason (for example anonymous, or no contact details)		

11 Closure and sign-off

Before closing

☐ Every market in section 6 decided; reports sent or the reason not to report recorded
☐ MDR event file clearly identified within the complaint file (803.18(e)) ☐ Complaint counted in the trend data
☐ Linked NCR and CAPA status checked ☐ Reply sent or reason recorded ☐ Records marked confidential where chosen (820.35(d))

Role	Name	Signature	Date
Complaint handler			
Investigator			
Regulatory reviewer (reportability)			
Quality approver			

Date closed	Where this record and its MDR event file are kept (system, folder)	Retention under your procedure
-------------	--	--------------------------------

Record	Period the text states	Source
US MDR event file (manufacturer or importer)	2 years from the date of the event, or the expected life of the device if longer	21 CFR 803.18(c)
US record of a correction or removal that was not reported	2 years beyond the expected life of the device	21 CFR 806.20(c)

Retention under ISO 13485 (clause 4.2.5, Control of records) and under the rules of other markets is not printed here: take those periods from your procedure. The form states no other period.