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STANDARDS & GUIDANCE REPORT · EUROPEAN UNION · EU REGULATION

EU MDR Articles 83–92

Regulation (EU) 2017/745 — Post-market surveillance, vigilance, and market surveillance

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IN FORCE The EUDAMED vigilance and post-market surveillance module is still to be declared functional, so serious incidents are reported to national competent authorities in the meantime. **Next:** Watch for the Commission notice that brings the EUDAMED vigilance module into mandatory use.

What It Covers

The manufacturer's duty to keep collecting and acting on real-world data for every device, the reports that come out of it, and the deadlines for reporting serious incidents and field safety corrective actions.

Who It Applies To

All manufacturers of devices on the EU market, in proportion to the device's risk class.

Key Requirements

- A post-market surveillance system proportionate to the risk class (Article 83) and a PMS plan (Article 84, Annex III).
- A PMS report for class I devices, updated when necessary (Article 85).
- A periodic safety update report: at least every two years for class IIa, at least annually for class IIb and III (Article 86).
- Serious incidents reported within 15 days of awareness, 10 days for a death or unanticipated serious deterioration, and 2 days for a serious public health threat (Article 87).
- Trend reporting of statistically significant increases in non-serious incidents or expected side effects (Article 88).

Structure at a Glance

PART	TOPIC	WHAT IT ASKS FOR
Art. 83	Post-market surveillance system	Planned, established, documented, implemented and maintained, proportionate to risk class.
Art. 84	PMS plan	The plan, as part of the technical documentation (Annex III).
Art. 85	PMS report	For class I devices; updated when necessary.
Art. 86	Periodic safety update report	For class IIa (at least every two years), IIb, and III (at least annually).
Art. 87	Reporting of serious incidents and FSCA	Deadlines of 15, 10, and 2 days from awareness.

PART	TOPIC	WHAT IT ASKS FOR
Art. 88	Trend reporting	Statistically significant increases in non-serious incidents or expected side effects.
Art. 89	Analysis of serious incidents and FSCA	The manufacturer's investigation, with the competent authority.
Art. 90–92	Analysis of vigilance data and the electronic system	Commission and authority analysis, and EUDAMED.

What an Auditor Asks to See

- The PMS plan for a chosen device, and the data sources it names.
- The latest PMS report or PSUR, and the decisions that came out of it.
- Vigilance files with the awareness date and the reporting clock for each serious incident.
- The trend reporting method and its thresholds.

Requirements Checklist

Work down the list with the evidence in hand; write where each item is evidenced in the right-hand column.

#	REQUIREMENT	EVIDENCE ON FILE
1	PMS procedure covering collection, analysis, conclusions, and actions for every device.	
2	PMS plan per device or family naming sources: complaints, service, literature, registries, similar devices.	
3	Indicators and thresholds defined for benefit-risk and for trend reporting.	
4	PMS report (class I) or PSUR (IIa, IIb, III) on schedule, with conclusions.	
5	PSURs for class III and implantable devices submitted through the electronic system to the notified body.	
6	Vigilance procedure with the 2-, 10-, and 15-day clocks and the awareness date defined.	
7	Field safety corrective actions and field safety notices controlled and traceable.	
8	Links from PMS findings to the risk management file, clinical evaluation, and CAPA.	
9	Post-market clinical follow-up planned or justified as not needed.	
10	Updates to the technical documentation when PMS changes a conclusion.	

Implementation Roadmap

1. Inventory	List every device and its class, and the PMS output each one needs.
2. Plan	Write or refresh the PMS plan for each device or family.
3. Wire it	Connect complaints, service, literature, and registries to the plan with owners and dates.
4. Report	Produce the PMS report or PSUR on schedule and act on its conclusions.
5. Practice vigilance	Rehearse a serious incident against the clock before a real one arrives.

How It Fits With Other Requirements

PMS is where ISO 13485 feedback and complaint handling, ISO 14971 production and post-production review, and the MDR clinical evaluation meet. ISO/TR 20416 gives guidance on post-market surveillance. US manufacturers will recognize the vigilance duties from 21 CFR 803, but the clocks and the definitions differ.

Findings We See Most Often

- PMS plans copied between devices without changing the sources or the indicators.
- Awareness dates set when the complaint was logged, not when the company knew.
- PSURs with data and no benefit-risk conclusion.
- Trend reporting described in the procedure and never calculated.

Where Systems Fall Short

- A PMS plan that lists data sources nobody actually reviews.
- PSURs that summarize data without reaching a conclusion on benefit-risk.
- No defined threshold for trend reporting.

How QES helps. A PMS plan, procedure and report templates built to run, not just to file. See the PMS plan build: qesisbest.com/services.html#pms-build · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. EUR-Lex — Regulation (EU) 2017/745 on medical devices — eur-lex.europa.eu/eli/reg/2017/745/oj; DNV — EUDAMED mandatory use — www.dnv.com/article/eudamed-mandatory-use-what-manufacturers-need-to-know.

A summary for orientation, prepared by Quality Excellence Services. It does not reproduce or replace the standard or regulation: read the official text, which governs. Not legal advice.