Medical Device Complaint Reportability & Cross-Market Assessment Checklist

1. Complaint & Event

- What happened, when, where, and how was the device being used?
- Device, model, lot/serial number and event details are documented.
- Relevant evidence and supporting information are available.

2. Patient / User Outcome

- Death, serious injury or serious deterioration was assessed.
- Hospitalization, medical intervention or impairment was considered.
- Delayed diagnosis/treatment, incorrect results or near-miss was assessed.
- No actual injury was confirmed where applicable.

3. Device Contribution & Malfunction

- Did the device cause or contribute to the event?
- Did it fail to perform as intended or malfunction?
- Were software, alarms, components, labeling or packaging involved?
- Could the failure recur and cause serious harm?

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4. Reportability Assessment

- Similar complaints/events were reviewed.
- Applicable reporting criteria were assessed.
- Reporting deadline/timeline was identified.
- Reportability rationale was documented and approved.

5. Market & Regulatory Responsibility

- Market(s) affected by the event were identified.
- Applicable authority/reporting framework was identified.
- Responsible manufacturer, importer, sponsor or other entity was identified.
- Potential impact on other markets was assessed.

6. Required Actions

- Regulatory report submitted, if required.
- Additional information/follow-up initiated, if needed.
- CAPA and risk-management impact assessed.
- Supplier, engineering/change and maintenance impact assessed.
- PMS/trending and field-action implications assessed.
- Complaint closure is documented and inspection-ready.