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1. Purpose

This procedure defines the processes for distributors to handle and assist Legal Manufacturer in reporting serious incidents related to guide wires to local Competent Authorities, ensuring compliance with EU Medical Device Regulation (MDR 2017/745) Articles 10, 14 and 87–92.

2. Scope

This procedure applies to all distributors of guidewires authorized by SP Medical within the European Economic Area (EEA). It includes the detection, registration, and the obligation to assist SP Medical as Legal Manufacturer in connection with reporting of vigilance cases to local Competent Authorities (CAs).

3. Definitions

This list contains definitions of abbreviations and terms used in this document.

Term	Description
Distributor	Any natural or legal person in the supply chain who makes a device available in the EU market, excluding importers and manufacturers (Article 2(34)).
Legal Manufacturer	Any natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured, or fully refurbished, and markets that device under its name or trademark.
Field Safety Corrective Action (FSCA)	Risk mitigation actions, including recalls or updates to device labeling/IFU (Article 2(68)).
Incident	Any malfunction or deterioration in device performance, inadequacy of the labeling/IFU, or any event posing risks to health.
Serious incident	Incidents resulting in death, serious health deterioration, or threat to serious public health (Article 2(65)).

4. Responsibilities

Below is a list of the division of responsibilities between distributor and Legal Manufacturer.

Responsible	Area of responsibility
Distributor	▪ Act as a point of contact for healthcare providers and end-users regarding incidents. ▪ Notify the Legal Manufacturer promptly of all potential incidents. ▪ Collaborate closely with the Legal Manufacturer to ensure timely and accurate reporting to the relevant Competent Authority. ▪ Maintain vigilance records in alignment with MDR Article 13(6). ▪ Identify and communicate local Competent Authority (CA) contact points and registration requirements.
Legal Manufacturer	▪ Vigilance responsibility. ▪ Ensure registration of serious incidents for their products. ▪ Evaluate all incidents for their category and vigilance reportability.

5. Procedure

5.1 Identifying Reporting Channels and Requirements for Competent Authorities

5.1.1 Identification of Local Competent Authority

The distributor must maintain an up-to-date list of Competent Authorities (CAs) in the Member States where the devices are distributed, including:

- Authority name and contact details.
- Website and specific online reporting portals (if applicable).
- Reporting email addresses or submission systems.

Ensure that the list specifies:

- Emergency contact details for urgent incidents (e.g., phone numbers for immediate reporting of public health threats).
- Language preferences for each Competent Authority.

5.1.2 Determining Local Reporting Process

For each Member State, identify:

- Whether the Competent Authority uses EUDAMED's vigilance module or its own reporting platform.
- Local reporting formats, forms, or templates required by the CA.
- Any supplementary documentation required (e.g., copies of the Field Safety Notice, device history records).

5.1.3 Language Requirements for Incident Reports

All incident reports must be submitted in the language required by the Competent Authority of the Member State where the incident occurred.

- In most cases, reports must be in the **official language(s)** of the Member State or in **English**, if accepted.

Confirm language preferences for follow-up reports and additional documentation directly with the local CA.

5.1.4 Pre-Submission Checklist for Incident Reports

Before submission, verify the report includes:

- Legal Manufacturer and distributor identification details.
- Complete incident description, including device and patient details.
- Information on any similar incidents previously reported.
- Initial and proposed corrective actions.
- Translations of key sections if required.

5.1.5 Regular Review of Reporting Requirements

The distributor must periodically (at least annually) review and update information on local reporting channels, including any changes in Competent Authority processes or language requirements.
Updates must be documented in the Vigilance Register and Legal Manufacturer must be informed of any significant changes.

5.1.6 Guidance for Staff

Distributors must provide clear instructions and reference materials for staff responsible for vigilance activities, including:

- Quick-reference guides for identifying the appropriate Competent Authority.
- Instructions for accessing and using local reporting platforms.
- Guidance on language compliance and translation services.

5.1.7 Escalation for Unclear Requirements

If reporting requirements in a Member State are unclear or unavailable, contact the local Competent Authority directly for clarification.
Inform the Legal Manufacturer immediately of any challenges in meeting local requirements.

5.2 Incident Detection and Reporting

Distributors must establish clear channels for receiving complaints or reports from healthcare providers, patients, or other stakeholders.

5.2.1 Receiving Incident Reports

Healthcare providers, patients, or other stakeholders may report potential incidents to the distributor via designated communication channels (e.g., phone, email, or an online form).

Use an **Incident Reporting Form** to document:

- Device identification (model, batch/lot, serial number).
- Reporter's details.
- Date and location of the incident.
- Description of the medical procedure and patient health condition prior to the procedure.
- Description of the incident, including patient outcomes.

Acknowledge receipt of the report within **24 hours** to the reporter.

5.2.2 Preliminary Triage

Review the report to determine if immediate action is required (e.g., public health threats).
Notify the Legal Manufacturer within **24 hours** of receiving the report, including all documented details.

5.3 Assessment and Collaboration with the Legal Manufacturer

5.3.1 Incident Assessment

Assist the Legal Manufacturer, who will evaluate the incident to:

- Confirm whether the event qualifies as a serious incident under MDR Article 87.
- Classify the event as reportable or non-reportable.
- Determine whether additional information is needed from the reporter or healthcare provider.

5.3.2 Legal Manufacturer Guidance

Follow the Legal Manufacturer's instructions on further investigation or corrective actions, as needed.

5.4 Reporting to Local Competent Authorities

5.4.1 Preparation of the Incident Report

Based on the Legal Manufacturer's assessment, the incident report is prepared using the Competent Authority's specific reporting format or the EUDAMED Vigilance Module (if operational).
Include all required details as per MDR Annex III, including:

- Distributor and Legal Manufacturer information.
- Device description (name, model, UDI, batch/lot number).
- Date, time, and location of the incident.
- Summary of the incident, including patient outcome.
- Corrective actions planned or implemented.
- Any similar previous incidents.

5.4.2 Serious Incident

Serious incidents must be reported to the local Competent Authority by the Legal Manufacturer in the Member State where the incident occurred.

- Reporting timelines must follow MDR Article 87:
  - **2 days**: For public health threats.
  - **10 days**: For incidents causing death or unanticipated serious deterioration in health.
  - **15 days**: For all other serious incidents.
- Reports must include:
  - Legal Manufacturer's details and EUDAMED registration number.
  - Description of the incident, including patient outcome.
  - Corrective/preventive measures planned or taken.
  - Reference to previous similar incidents, if any.

5.4.3 Acknowledgment from the Competent Authority

Retain acknowledgment or receipt confirmation from the Competent Authority (if this is received) as part of the vigilance record. Share this acknowledgment with the Legal Manufacturer.

5.4.4 Follow-up Reporting and Updates

- **Investigation Progress:**
  - Assist the Legal Manufacturer in any additional investigations by:
    - Facilitating the collection and return of defective devices for Legal Manufacturer investigation.
    - Gathering additional information from healthcare providers, as requested.
  - Share findings with the Legal Manufacturer promptly for incorporation into follow-up reports.

- **Submitting Follow-Up Reports:**
  - For ongoing cases, submit follow-up reports to the local Competent Authority when:
    - New information becomes available.
    - Investigation findings require updates to previously submitted details.

5.4.5 FSCA Reporting

If an FSCA is required, the distributor must assist in disseminating Field Safety Notices (FSNs) and implementing actions locally.

- **FSCA Implementation:**
  - Distribute Field Safety Notices (FSNs) to all affected stakeholders, including healthcare providers and distributors within the Member State.
  - Ensure timely execution of FSCA actions, such as:
    - Device recalls or replacements.
    - Updates to labelling, instructions for use (IFUs), or risk management measures.
- **FSCA Reporting to Authorities:**
  - Submit FSCA-related documentation to the local Competent Authority if this is requested, including:
    - Action plan and implementation timelines.
    - Confirmation of FSN distribution.
    - Progress reports, if required.

5.5 Communication with Competent Authority

The distributor shall maintain open and continuous communication with the Legal Manufacturer to:

- Share updates on ongoing investigations and corrective actions.
- Provide feedback from healthcare providers and users regarding the FSCA.
- Support the submission of follow-up reports to Competent Authorities as required.

5.6 Incident Investigation

The distributor assists the Legal Manufacturer in incident investigations by:

- Facilitating the return of defective devices for analysis.
- Collecting additional information from end-users or healthcare providers.
- Providing local expertise and market-specific insights.

5.7 Documentation and Record Keeping

The distributor must maintain accurate records of all vigilance activities, including:

- Incident reports.
- Correspondence with the Legal Manufacturer and Competent Authorities.
- Copies of submitted incident reports and FSNs.
- FSCA communications and implementation records.

Records must be retained for at least **10 years** (or **15 years** for implantable devices) in accordance with MDR Article 13(6).
Retain all vigilance records for a minimum of **10 years** (or **15 years** for implantable devices) in compliance with MDR Article 13(6).

5.8 Trending and Proactive Measures

Distributors shall contribute to trend analysis by submitting periodic summaries of complaints and incidents to the Legal Manufacturer.

Collaborate on identifying emerging risks and implementing proactive measures in the supply chain.

Participate in joint reviews of vigilance data to implement proactive risk management measures.

6. Training

Distributors must ensure that all relevant staff members are trained on:

- MDR vigilance requirements, specifically Articles 14 and 87–92.
- Internal procedures for handling and reporting incidents.
- Responsibilities related to FSCA implementation.

7. Mandatory records

Following records must be established:

Records	Records
▪ Updated list of contacts to local Competent Authorities. ▪ Records of employee training. ▪ Records of customers. ▪ Records documenting purchased, sold, and distributed devices.	▪ Records of complains / incidents. ▪ Records of serious incident reports. ▪ Trending records. ▪ Correspondence with the Legal Manufacturer and Competent Authorities. ▪ FSCA communications and implementation records.

8. References

This procedure is elaborated to ensure compliance with requirements stated in following:

#	*Document number*	Title
1	MDR 2027/745/EU	▪ Article 10 (General Obligations of Manufacturers). ▪ Article 14 (Obligations of Distributors). ▪ Articles 87–92 (Vigilance and Incident Reporting). ▪ Annex III and Annex XIV (Post-Market Surveillance).
2	ISO 13485:2016	Quality management system requirements for medical devices.
3	ISO 14971:2019	Risk management for medical devices.
4	MEDDEV 2.12-1 Rev. 8	Guidelines for a medical device vigilance system.

9. Change log

Version	Author	Date	Change description
01	PJD	2025-01-27	New document