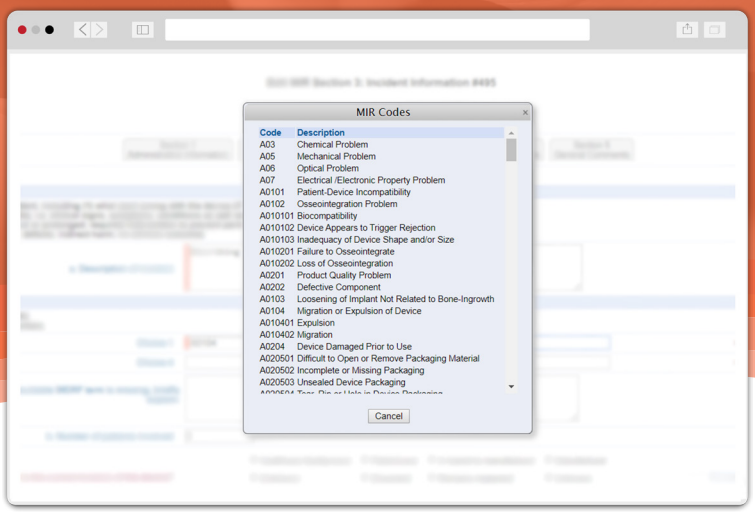
DATASHEET

Automated Process for EU MIR Submissions

The AssurX EU MDR enables electronic reporting of medical device vigilance events required by manufacturers, user facilities and importers in compliance with European Union Medical Device Regulation (EU MDR) and requirements of the Manufacturer Incident Report form (MIR). The EU MDR solution can run standalone or integrated with our modern post-market surveillance quality management system for unmatched visibility into the device history.



For post-market incident submissions, AssurX offers the Manufacturer Incident Report (MIR) within the solution for efficient and compliant reporting of applicable medical device vigilance incidents.

The AssurX MIR aligns business logic with the latest Manufacturer Incident Report template as published by the European Commission.

Submission Automation for Accuracy and Compliance

Empowers medical device companies to document and submit according to EU Vigilance guidelines and reporting timeframes. MIR data is collected through the lifecycle of the medical device or drug delivery system. Integrate with key source systems to centralize data in a secure repository for downstream activity such as post-market investigations and reporting.

Create full transparency of each incident, determination of reportability, as well as documented justifications for non-reportable events.

Centralized, Efficient MIR Submission and Traceability

Helps ensure information accuracy and timeliness of submissions with built-in features that include:

- Dashboards, charts, or graphs for visibility and tracking
- Electronic signature approvals for any step within the reporting cycle
- Alerts and notifications to keep tasks on schedule
- Pre-populated Annex, Patient Information, and Manufacturing Analysis Codes that eliminate the need for manual lookup and reference to other documentation
- XML or PDF generated output for automated reviews within the company or with the registered agent

Benefits of Assurx MIR for EU MDR

- Rapid implementation with a pre-configured solution
- Automation of report completion and submission
- Connectivity to device complaint
- Improves transparency aligned with current and future EU MDR requirements
- Irrefutable audit trail for tracking changes and approvals

UDI Data Readiness

Rather than require that post-market surveillance teams manually enter data, integrate with key source systems to centralize UDI data values to streamline report completion.

Create One Unified System of Interconnected Processes

AssurX MIR for EU MDR integrates with other AssurX solutions or external systems to manage quality and change throughout the device lifecycle including:

- Complaint Handling
- Corrective and Preventive Action
- Supplier Quality
- Document Management
- Training Management
- Change Control

Connect MIR reports to product records in external complaint and vigilance systems. Integration increases the control of data throughout the enterprise and creates a quality ecosystem focused on visibility, product safety/improvements and customer satisfaction.