ASSURX EUROPEAN UNION MEDICAL DEVICE REQUIREMENTS REPORTING (EU MDR)

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 Manufacturing 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.

AssurX software enables reporting compliance for medical device manufacturers under European Union Medical Device Regulation (EU MDR). Addresses the European Union Medical Device Regulation (EU MDR) reporting compliance with agility and integrity.

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

AssurX MIR 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

AssurX MIR 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

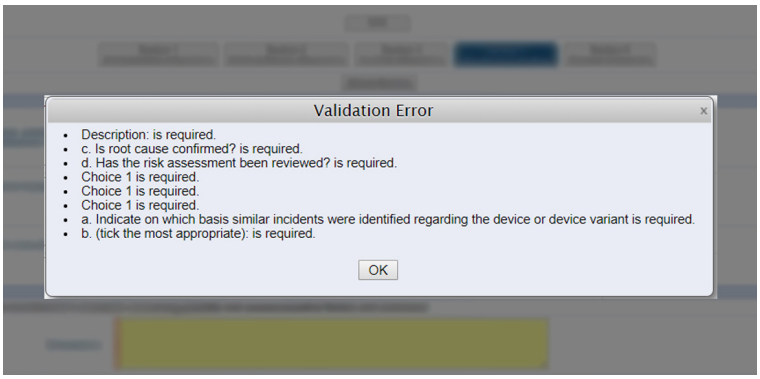
BENEFITS OF ASSURX MIR FOR EU MDR

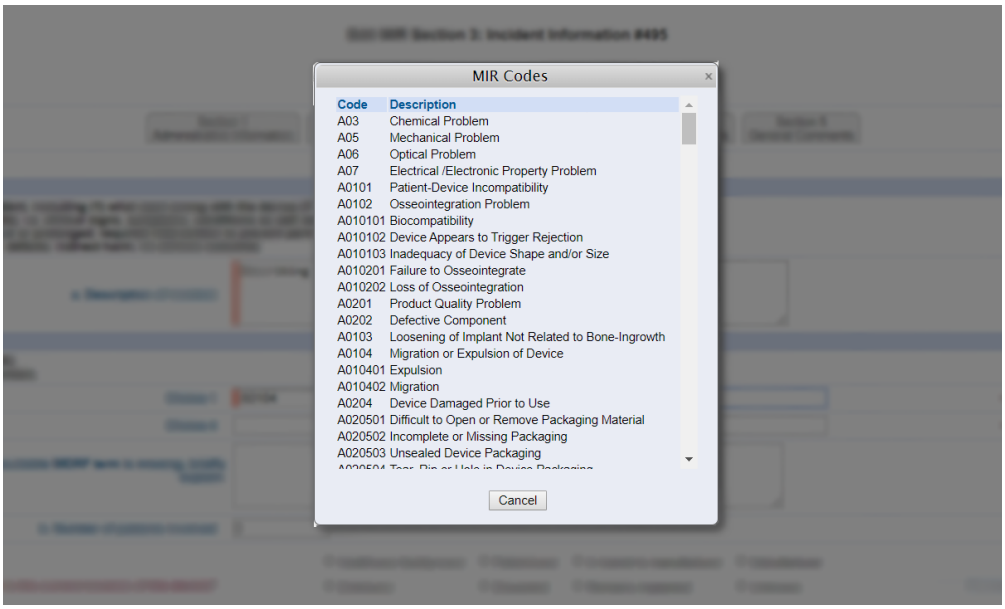
+ Rapid implementation with a pre-configured solution
+ Automation of report completion and submission
+ Provides connectivity to device complaint
+ Improves transparency aligned with current and future EU MDR requirements
+ Improves clarity of trend reporting
+ Irrefutable audit trail for tracking changes and approvals
+ Integration with other AssurX solutions or enterprise systems for end-to-end visibility

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.

The AssurX EU MDR solution provides form validation guides to guide users to complete all mandatory fields based on the reporting type.





Pre-populated code lists promote process efficiencies and accuracy.

CREATE ONE UNIFIED SYSTEM OF INTERCONNECTED PROCESSES

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

- Complaint Handling
- Corrective and Prevention 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.

Reference: Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (MDD/AIMDD/IVDD): https://ec.europa.eu/docsroom/documents/33464

ABOUT ASSURX

With decades of expertise built into our quality management and regulatory compliance software platform, AssurX helps companies maintain quality and compliance, streamline workflow, control risks and better manage any enterprise.

Our incredibly configurable software and deep understanding of users' needs produce a unique system that easily adapts as your business evolves. AssurX is an ideal partner for regulated companies looking for better operational control and efficiency while staying compliant.

To learn more about how AssurX can help with your quality and regulatory compliance management needs, please call 1-888-9-ASSURX or request an online demonstration.