Innovit MDR Connector*

SINGLE GATEWAY FOR REGULATORY SUBMISSION TO EUDAMED

Following the implementation of the Unique Device Identifier (UDI) regulation in America, other countries and regions are now fast-tracking the adoption of medical device regulations in their respective jurisdictions. Next one up with significant implications is the European Union which has set a compliance date of May 2020. The EU's Medical Device Regulation (MDR) went into effect in May of 2017 to establish greater control and transparency on the quality and safety of medical devices manufactured or imported to the EU. A key component of the MDR regulation is the European Database on Medical Devices (EUDAMED) that collects certain medical device data from manufacturers and makes them accessible to the public. Unlike the FDA's Global Unique Device Identification Database (GUDID), EUDAMED requires more extensive data including unstructured information related to clinical investigations, safety & performance studies, vigilance and market surveillance. As such, the UDI data required by the FDA is just one of six modules covered in EUDAMED, which are:

- Actor Registration
- Device Registration (UDI)
- Notified Bodies & Certificates
- Clinical Investigations & Performance Studies
- Vigilance
- Market Surveillance

As stakeholders await the final technical specifications from the European Commission on EUDAMED, manufacturers are scrambling to understand the requirements, collect the relevant data and establish a process to submit data to EUDAMED under pressing time constraints.

Innovit's MDR Connector solves these challenges by allowing device manufacturers to implement a "global system and unified process" that is fully integrated with internal systems for submitting both structured and unstructured data to EUDAMED.

"Innovit MDR Connector enables organizations achieve timely compliance with EU MDR regulations."

INNOVIT MDR CONNECTOR

Innovit's MDR Connector is a GAMP5 validated, 21 CFR Part 11 and Annex 11 compliant solution that allows device manufacturers to submit structured and unstructured data to EUDAMED**. Manufacturers automatically get a pre-packaged list of device attributes, code lists and validation rules for submission to EUDAMED. Furthermore, manufacturers can import, associate and submit regulatory documents that are linked to a device through the Basic UDI Device Identifier. Innovit's MDR Connector also automates the submission of data in the specific data format and messaging protocol required by the regulatory agency (i.e. AS4 protocols and SOAP XML). A complete message exchange history is also stored in Innovit's solution to provide data stewards in Regulatory Affairs and Quality Assurance with full visibility and traceability of their data submission history.

* **Solution pending technical specifications from the European Commission**

** **Development of MDR Connector for relevant Modules is prioritized based on the volume of data submitted with the UDI Module being first priority**

CAPABILITY HIGHLIGHTS

Data Import	Centralized structured and unstructured data
Data Maintenance	Pre-configured EUDAMED UDI attributes
	Pre-configured EUDAMED UDI attribute code lists
	Pre-configured EUDAMED UDI attribute validation rules
	Management of Basic UDI DI (BUDI) and Single Registration Numbers (SRNs)
	Management and submission of regulatory documents including Periodic Safety Update Reports (PSURs), Serious Incidents (SIs), Field Safety Corrective Actions (FSCAs), Trend Reports (TRs) and Field Safety Notices (FSNs)
	Risk classification management
Data Governance	Data validations
	Workflow processes for data enrichment and approval
	Granular role-based security
	Audit trail for data and message exchange history
	e-Signature for full approval traceability
Data Submission	EUDAMED
	AS4 protocols and SOAP XML

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HOSTING

Different hosting options are available for customers.

- **Hybrid Cloud:** Shared server but dedicated environment
- **Public Cloud:** Multi-tenanted with shared server and shared environment
- **Private Cloud:** Dedicated server and dedicated environment

BENEFITS

- Achieve compliance with EUDAMED submission requirements
- Centralize data validation and submission
- Enhance data quality and governance
- Reduce operational and IT cost

ABOUT INNOVIT

Innovit's globally certified product data management solutions protect revenue streams, reduce supply chain costs, improve online product marketing effectiveness and ensure regulatory compliance. Delivering the fastest time to value for a complete end-to-end solution with preconfigured modules that have out of-the-box data validation, the broadest global coverage for data synchronization, and publication capabilities to support maximum syndication advantage for omni-channel ecommerce. Operating since 2000, Innovit is based in San Francisco CA with offices in London, Sydney and Melbourne and customers such as Johnson & Johnson, Kellogg's, 3M, Colgate Palmolive and B. Braun across diverse industries including healthcare, CPG and automotive aftermarket.