



EudaMed





INTRODUCTION

Eudamed.eu is in the unique position of being the only company in the world to have had hands on experience in, not only managing the MDR EUDAMED development but also in guiding the related European Commission (EC) decisions. Within the EC, we were in the middle of the design, architecture, implementation, delivery and team management of MDR Eudamed.

If you need help with MDR EUDAMED, please do not hesitate in contacting us.

Eudamed.eu Services



Training



EudaMed+
Machine-to-Machine



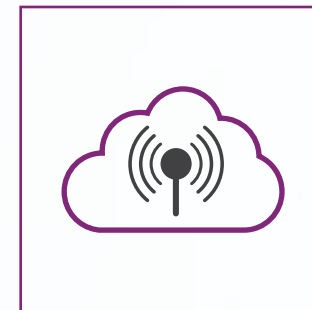
EudaMed SaaS
and Templates



Support



Consultancy



Access Points and
Application Integration

Exclusive Training



Compliance with MDR EUDAMED requires both companywide change management and an IT project. Effective change management relies on good inter-company communications. Good communication requires all involved departments to have the same understanding of requirements, terminology and planned outcomes. To assist with these communication needs, Eudamed.eu is providing an exclusive and comprehensive MDR EUDAMED training course. This is designed for Management, RA/QA, and IT personnel in addition to any interested people.

This course is unique to Eudamed.eu no other company is providing such a comprehensive training opportunity.

Eudamed.eu provide exclusive training

This training gives the participants a complete understanding of the MDR EUDAMED data elements, forms, requirements and inner workings in plain, non-technical language. It includes a comprehensive overview of the data entry and data upload options, the initial Actor registration, and the UDI Device data requirements.

In addition to comprehensive explanations on the front end web inputs, the training provides participants with a full understanding of the XSD and XML requirements. We cover the machine-to-machine requirements, the manual bulk upload of XML data, the service and data models, and the data exchange with all of its complexities including the automated acknowledgements and notifications. All is covered in understandable plain English so it is understandable by all, without IT jargon.

Following the training, participants will be able to communicate effectively on all facets of MDR EUDAMED with clients and IT teams.

The training is delivered over two half days and allows participants many different Q&A opportunities.

EudaMed+ Machine-to-Machine or Manual XML Upload



EudaMed+

- Removes the need for in-house IT developments.
- Exceptionally Cost-effective.
- Full machine-machine uploads or XML files for manual upload.
- Can operate across a group of companies with multiple SRN's
- Multi-user, multiple security levels, user-friendly environment.
- Securely installed and tested by Eudamed.eu on your servers.
- Easy to use input forms for improved data collection.
- UDI DI record cloning to reduce data inputs.
- Record locking – blocks further data inputs.
- Ability to confirm and record reviews per Basic UDI and UDI DI's.
- Validates data inputs on entry.
- Provides immediate validation and error checking.

Contact us now for a demo.



EudaMed SaaS and Templates

EudaMed SaaS

- Removes the need for in-house IT developments.
- Exceptionally Cost-effective.
- Special discounted package for less than 100 UDI DI's.
- Creates XML files ready for you to upload to MDR EUDAMED
- Provides PDF files for additional validation and error checking.
- Validates your uploaded data.
- Converts error-free data to XML.

Contact us now for a demo

EudaMed Templates

Available template packages MDR (MDR, MDD, SPP spreadsheets)
and IVDR (IVDR, IVDD spreadsheets)

Support Services



Eudamed.eu provides full support services for on-going MDR EUDAMED data upload, machine-to-machine, and access point issues, including MDR EUDAMED actor registration and user management.

Supporting companies with issues such as failed XML uploads, understanding changing requirements from the EC, and many more.



Consultancy

Eudamed.eu offers on- and off-site consulting services. Our knowledge can help your team's progress faster and assist with the IT project planning. Our exclusive knowledge of the inner working of MDR EUDAMED allows us to offer our clients unique insights into the systems complexities.

Our consultants can guide your team, lead your project, and assist with your solution architecture. In short, we can be involved, as much or as little, as our clients want us to be.

Access Points & Client Application Integration



For automated data submissions to MDR EUDAMED via machine-to-machine, a compatible access point is required. The EC provides a free access point client called Domibus. The costs in both time and money in preparing, supporting, on-going maintenance and monitoring of access points can be high.

Eudamed.eu offers several cost saving Access Point options for clients, including the option to use ours.


Integration of the EC's Domibus access point with client applications requires analysis and development of a custom Domibus plugin. The cost for the development of a custom plugin can vary substantially depending on the requirements and the complexity of the required plugin. We can assist you with this integration plugin. Based on our experience, this is normally a lot faster than in-house teams.



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