



**EudaMed**





# INTRODUCTION

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

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

# Eudamed.com Services



Training



EudaMed+  
Machine-to-Machine



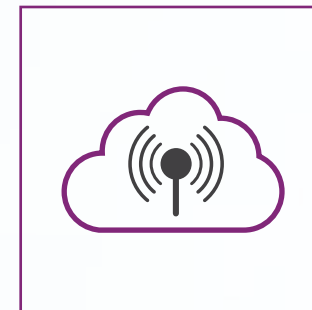
EudaMed SaaS  
and Templates



Support



Consultancy



Access Points and  
Application Integration

## Exclusive Training



Compliance with 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.com is providing an exclusive and comprehensive 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.com no other company is providing such an up to date and comprehensive training opportunity.

## Eudamed.com provide exclusive training

This training gives the participants a complete understanding of the 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 data 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 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.
- Automated data uploads.
- 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.com 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 free demo.



## EudaMed SaaS and Templates

### EudaMed SaaS

- Removes the need for in-house IT developments.
- Exceptionally Cost-effective automated uploads.
- 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 free demo

### EudaMed Template Packages

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

## Support Services



Eudamed.com provides full support services for on-going MDR EUDAMED data upload, machine-to-machine, and access point issues, including the 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.com offer 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 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 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.com 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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