



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 decisions. Within the European Commission, 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



Software and Templates



Support



Consultancy



Machine-to-Machine



Access Point
Application Integration

Training



Compliance with MDR Eudamed requires both a companywide change management and an IT project. Effective change management relies on good intercompany 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 two versions of their MDR Eudamed training, technical and non-technical.

These courses are unique to Eudamed.eu

Eudamed.eu provide two training options

- 1- Non-technical: This training gives the participants a complete understanding of the MDR Eudamed data elements, 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. Following the training, participants will be able to communicate effectively on all facets of MDR Eudamed with clients and IT teams.
- 2- Technical: The technical training provides the IT participants with a complete understanding of the technical MDR Eudamed data upload possibilities and requirements. The training provides participants with a full understanding of the XSD and XML requirements, the manual XML data upload, the service and data models, the machine-to-machine requirements, and the data exchange with all of its complexities including the automated acknowledgements and notifications.

Available on- or off-site, with online possibilities for manufacturers only.

Software and Templates



The total cost of ownership for an in-house IT MDR Eudamed project is substantial. To assist with the data preparation we have made our MDR/IVDR spreadsheet templates available to purchase.

The Eudamed.eu SaaS solution is an exceptionally cost effective solution to prepare, convert, and validate client data in addition to managing the EC data submissions. Our SaaS option converts your template data to the required EC XML, validates it against all the EC rules, and completes the EC data submissions. The SaaS option is for companies who do not want their own in-house IT solution with the large associated IT overheads.



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.

Machine-to-Machine Access Point Options



For automated data submissions to the EC via machine-to-machine, a CEF eDelivery 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.



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 Point Client Application Integration




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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