

Your Medical Device Data

Under the European medical device regulations, all medical devices placed on sale inside the European Union must be certified and medical device data must be added to EUDAMED, the European Medical Device Database.

EudaMed.com have two solutions to help you comply with the complex EUDAMED data requirements:

EudaMed SaaS



EudaMed+

In the cloud

Installed on your servers

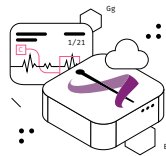
Adding your data to EUDAMED is a multi-step process and **EudaMed.com** have automated it as much as possible.

DATA ENTRY

EudaMed SaaS is populated directly from the EudaMed.com spreadsheet templates or from your data filled JSON files.

EudaMed+ can be populated directly from spreadsheet templates and/or web-based forms which include many functionalities and data management tools to help users.

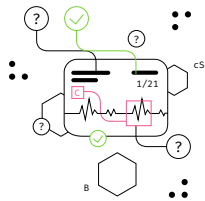
1



DATA VALIDATION

Both **EudaMed+** and **EudaMed SaaS** validate your data against 100s of data and complex business rules. You receive PDF files of your device data highlighting errors and any failed business rules which allow you to easily validate your data.

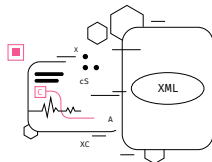
2



DATA CONVERSION

After error-free data validation, your data is converted to the EUDAMED required XML formats. Includes full batch management.

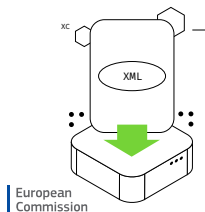
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DATA SUBMISSION

When the XML files are ready EudaMed+ and EudaMed SaaS submit your data to EUDAMED.

4

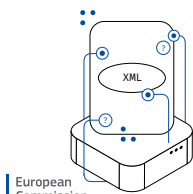


European Commission

EUDAMED RESPONSE

EUDAMED will return messages of success or failure.

5

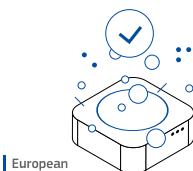


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SUCCESS

Your data is added to EUDAMED.

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European Commission

*If unsuccessful you fix the data and we send it again for you



EudaMed+ and **EudaMed SaaS** are always up to date.

If the European Commission changes the data requirements
EudaMed.com rapidly implement the changes.

Using the **EudaMed.com** software services you have...

- No in-house development costs
- No access point costs or worries
- No upgrade worries