WARNING!

YOUR AR CAN TAKE YOU OUT OF THE EU/UK BUSINESS!

Our vision is simple: Your Authorized Representative ("AR") must comply with certain Articles of the EU REGULATION (EU) 2017/745, 2017/746 and UK-MHRA Directives for you to be able to market your devices in Europe/UK. Failure to comply with these regulations may result in your product being recalled from the market.

We know that all manufacturing companies have different needs from day to day, and they trust the words of the European ARs. But it is important that your AR provide affirmative answers to the following request:

1. Do you comply with the EU REGULATION (EU) 2017/745, Articles 27, 29 and 31?
2. Do you have a compliance verification procedure for
   – CE marking in the case of Class IIa, IIb and III devices?
   – Verification of the ISO 13485 compliance for Class I devices?
3. Do you have a verification procedure of ISO 13485 certification for Class IIa, IIb, or III?
4. Do you have a verified Complaint and Reporting procedure?

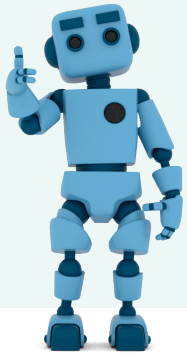
This information is not only important, it is mandatory because your AR can be cancelled for 2 reasons:

1. Your AR does not fulfill the basic functions stipulated in the Medical Device Regulation (EU) 2017/745.
2. A client of your RA does not meet the appropriate quality standards.

Yes, your EU/UK Authorized Representative can be cancelled for non-compliance of another client!

Why RQMIS is your Best Option?
No hidden fees!

Our procedures comply with EU REGULATION (EU) 2017/745 for AR companies. Our prices are competitive with other ARs, BUT our basic price structure includes ALL of the required responsibilities of an AR.



RQMIS

Comparision of RQMIS vs. Other Companies

Medical Device Regulation (EU) 2017/745	RQMIS	Other companies (*)
Basic Fee	------	3,000 USD Class I 4,000 USD Class IIa/IIb 4,500 USD Class III
Documentation		
Verification of the Declaration of Conformity.	In the quotation	Extra fee (2,500 USD)
Technical documentation supporting review on behalf of CE marking compliance.		Extra fee (350 USD/h)
Keep required documentation (i.e. Declaration of Conformity, Technical Documentation, certificates/amendments issued by Notified Body) at disposal of competent authorities – minimum of ten years, fifteen for implantable devices.		Extra fee (2,000 USD)
Registration		
Register the product with a European Health Authority.	In the quotation	In the quotation
Ensure client is in compliance with registration of Unique Device Identification (UDI) according to Article 27.		Extra fee (1,500 USD)
Ensure registration of device is performed according to Article 29.		
Ensure registration of client and importers are completed according to Article 31.		
Authorities Communications		
Being able to provide the requested information by competent authorities.	In the quotation	Extra fee (350 USD/h)
Having the internal tools to keep client informed of any requests from competent authorities.		
Ensure competent authorities are given access to device and cooperate with competent authorities regarding any preventive or corrective action taken to remove or mitigate risks posed by devices.		
Internal Audit Support		
In the case of Class I Medical Devices, Conduct MDR Compliance Audits of Client (Remote).	In the quotation	Extra fee (350 USD/h)
Conduct an internal audit for providing the AR Certification (not official) based on 21CFR820 and ISO13485 for Class I devices (Remote).		
Conduct UDI Compliance Audit (Remote).		
Vigilance Reporting		
Ability to inform client of complaint/reports related to suspected incidents from healthcare professionals/patients/users.	In the quotation	Extra fee (350 USD/h)
Ability to Assist with Incident & FSCA (field safety corrective action) reporting.	Extra fee (250 USD/h)	
Compliance With All Our Clients		
Committed to terminate the AR service if any client acts contrary to their obligations under the EU-MDR 2017/745, in order to avoid prejudicing current clients.	We mention this in our contracts. No extra fees.	Extra fee 5,000 USD
Administrative		
Protect your privacy and your Know-how providing secure online access to all client documentation and regulatory information as required.	In the quotation	Not mentioned

(*) According to the EU Data Protection Law we cannot mention the names of other companies in our Website.

RQMIS FEES:

Class I:

All years 9,000 USD

Class IIa, IIb and III:

1st year: 11,000 USD*

Other years (without CE mark renew): 7,000 USD

Other years (with CE mark renew): 9,000 USD

* if RQMIS is in charge of writing the Technical Document or Clinical Evaluation Report the price will be reduced to 9,000 USD.

EXAMPLE:

Devices Classification	RQMIS	Other Companies
Class I device	9,000 USD	16,800 USD
Class IIa/IIb family products (one CE marking)	11,000 USD	18,500 USD
Class III family product (one CE marking)	11,000 USD	18,500 USD

RQMIS

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