

US MedTech Companies!

# take your step into the EU Medical Device Market

**With over 30 years of experience in the Medical Device Industry, we support you with 5 Steps to enter the European Market.**

The European Union is one of the largest and most important markets for medical devices worldwide. Entering the EU market requires compliance with the Medical Device Regulation (MDR) – an essential step for successful market entry or expansion. Be ahead and don't miss out on this one.



## Full of opportunities

The EU combines strict general safety and performance requirements (GSPRs) with CE-marked growth opportunities.

**If you want to grow globally, you need to be in Europe!**



## The right time is now!

Take advantage of our experience, our strong presence in Europe, and our tailored services.

**Step into the EU market, we guide you all the way!**

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**wqs** ✓  
MANAGEMENT CONSULTANTS

## Consulting. Registration. Market success.

WQS supports you from the initial idea to the successful implementation of your product in the European market and beyond. With locations in Germany, Florida, and California, our experienced contact persons are available to assist you at any time.  
*Contact us for your customized roadmap to success in Europe.*



### 1. Completing the Conformity Assessment Procedure

We guide you through EU registration with CE Certification and ISO 13485 for Medical Devices.



### 2. Appointing Your Authorized EU Representative

We act as your authorized Representative to ensure your MDR compliance and communicate with authorities.



### 3. Organization of Storage and Fulfillment in GER & USA

Compliant storage with labeling, dispatching and shipping for your sterile or regulated devices.



### 4. EUDAMED Registration with SRN Number application

We manage your EUDAMED registration and secure your Single Registration Number (SRN) for MDR compliance.



### 5. Start Selling & Stay Compliant

Your product is ready for the EU market!  
We remain by your side for Post-Market Surveillance & Monitoring to ensure long-term compliance.

