Quality First International

Your stepping stone from the drawing board to the patient

REGISTAR

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Many subtle yet critical changes are occurring in the medical device regulatory arena that could affect your business. One significant change that has recently impacted many medical device manufacturers is the transposition of the European Medical Device Directive into the national laws of new EU Member States manifesting in various effects:

- Use of her national language for medical device technical documentation submissions
- Registration schemes in order to control the placement of medical devices on the national market

The type and extent of the new requirement differ throughout the EU Member States. These new requirements in Europe could adversely impact the compliance of your medical device, potentially affecting sales.

In recognition of these challenges, Quality First International introduces Registar, an expansion of our registration services. Quality First International can provide a detailed review of registration and language requirements associated with marketing your medical devices in Europe. In addition, QFI will translate the relevant technical documentation, where required, register your medical devices and submit the necessary documentation to the appropriate authorities.

Registar Service Level 1	*Registar Service Level 2*
For each country of interest this service provides:	*For each medical device undergoing registration, this service level provides:*
A Country Registration Summary	*A device registration Action Plan*
A comprehensive review of country medical device registration	*Full submission of all application forms and corresponding documentation in the correct*
The language requirements for all Documentation required for medical	*Complete management of the*
Application forms and other Associated documentation	*A Detailed Report for the registration*

Any questions about your medical devices registration requirements?
Please call QUALITY FIRST INTERNATIONAL on +44 (0) 208 221 2361
OR email us on enquiries@qualityfirstint.com

Quality First International Limited

REGISTAR ENQUIRY FORM

FAX ENQUIRIES TO: +44 (0) 208 221 2361

Company name	
Address	
Country	*Zip code*
Contact name	*Telephone*
Fax	*Email*

★ *Registar Service Level 1* *Overview of Country Regulations*	★★ *Registar Service Level 2* *Full Registration Management*
For each country of interest, this service level provides: ★ *A comprehensive review of medical device registration regulations* ★ *The language requirements for all documentation required for medical device registration* ★ *A Country Registration Summary* ★ *Application forms and corresponding documentation*	*For each medical device undergoing registration, this service level provides:* ★ *A device registration Action Plan* ★ *The full submission of the medical device registration application to all countries agreed* ★ *Translation of the appropriate documentation* ★ *A detailed Registration Report for all countries of interest*
Please indicate the countries of interest	*Please indicate the countries of interest*

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