GEMAR

Medical Health Services

Reaching the market in time
A global approach for medical devices registration

Medical Device Regulatory Compliance Consultants

Services

- Due Diligence & Gap Analysis
- Global Regulatory Consulting for Medical Device and IVD Companies
- Strategic Planning Consulting
- Quality Management Systems
- Biocompatibility & Safety testing
- Creation of a Regulatory Dossier
- CE Marking
- 510K, Pre-IDE, PMA Submissions
- Risk Management ISO 14971
- Validation of IQ, OQ, PQ & Software
- Clinical (CRA) Support
- Quality Assurance &Regulatory Audits
- IEC 60601-1 (Third Edition)
- Vigilance & Post-Market Surveillance
- Post Market Clinical Follow-up
- Training

Gemar is an independent Medical Device Consulting firm, operating worldwide with extensive Regulatory Compliance Experience.

Global Medical Device Registration and Medical Device Approval

Gemar - Your US Agent and Correspondent

Gemar - Your European Authorized Representative (EAR)

Europe | The Americas | Asia

www.gemarmed.com

Gemar
Via G. Amendola 43
I-41046 Medolla (Mo) Italy

We bring you to market faster!