EmergoGroup.com

EMERGO
a UL company

Global Medical Device QA/RA Consulting

More than 2,800 companies trust Emergo to achieve and maintain compliance with global medical device and IVD regulations.

Core Areas of Expertise

Medical device/IVD registration

Emergo can help you gain access to markets in North and South America, Europe, the Middle East and Asia. We utilize years of hands-on experience to ensure that our clients get their products to market as efficiently as legally possible. Emergo can compile, submit and manage all of your device registrations worldwide.

In-country representation

Medical device regulations in most countries require foreign manufacturers to appoint an in-country representative to act as the point of contact for regulatory authorities and assist in device registrations and vigilance/adverse event reporting. Thousands of device companies have chosen Emergo for this important role because it allows them to maintain control over their device registrations and add/change distributors as needed.

QMS implementation and compliance

We develop, implement and maintain integrated quality management systems that comply with the US FDA Quality System Regulation (21 CFR Part 820), ISO 13485:2016, MDSAP, Japan Ordinance #169, Brazil GMP and other national quality system requirements. We also assist with gap analyses, due diligence, and internal, supplier, and pre-assessment audits. Our consultants guide you through every step of the process: writing custom procedures, conducting and monitoring the implementation and training your employees.

Regulatory consulting support

Emergo is fully prepared to assist you with many facets of regulatory compliance including:

- European MDR/IVDR strategy and transition
- Clinical Evaluation Reports (CER)
- Product grouping and classification
- Incident reporting and global vigilance
- Risk management and ISO 14971

International Medical Device and IVD Compliance Specialists

Medical device and IVD manufacturers — from startups launching their first device to multinationals maintaining compliance — choose Emergo as their partner for compliance with global regulations.

We open the door to 55+ countries worldwide

There is no need to work with multiple consulting firms or distributors in distant countries. Emergo offers a single-source solution for accessing established and emerging device markets. When you work with Emergo, you are tapping into the collective expertise of a global consulting team versed in many areas of regulatory compliance. Emergo maintains offices on five continents, and all of those offices are staffed by local teams with expertise in the unique regulatory requirements of their countries.

We understand how international regulations overlap

Because Emergo works in so many markets, we fully understand complex national regulations and how they overlap with one another. We apply this knowledge for your benefit in a way that could not be achieved by working with separate consultancies or affiliates with limited local expertise.

Project management teams keep projects on track and on budget

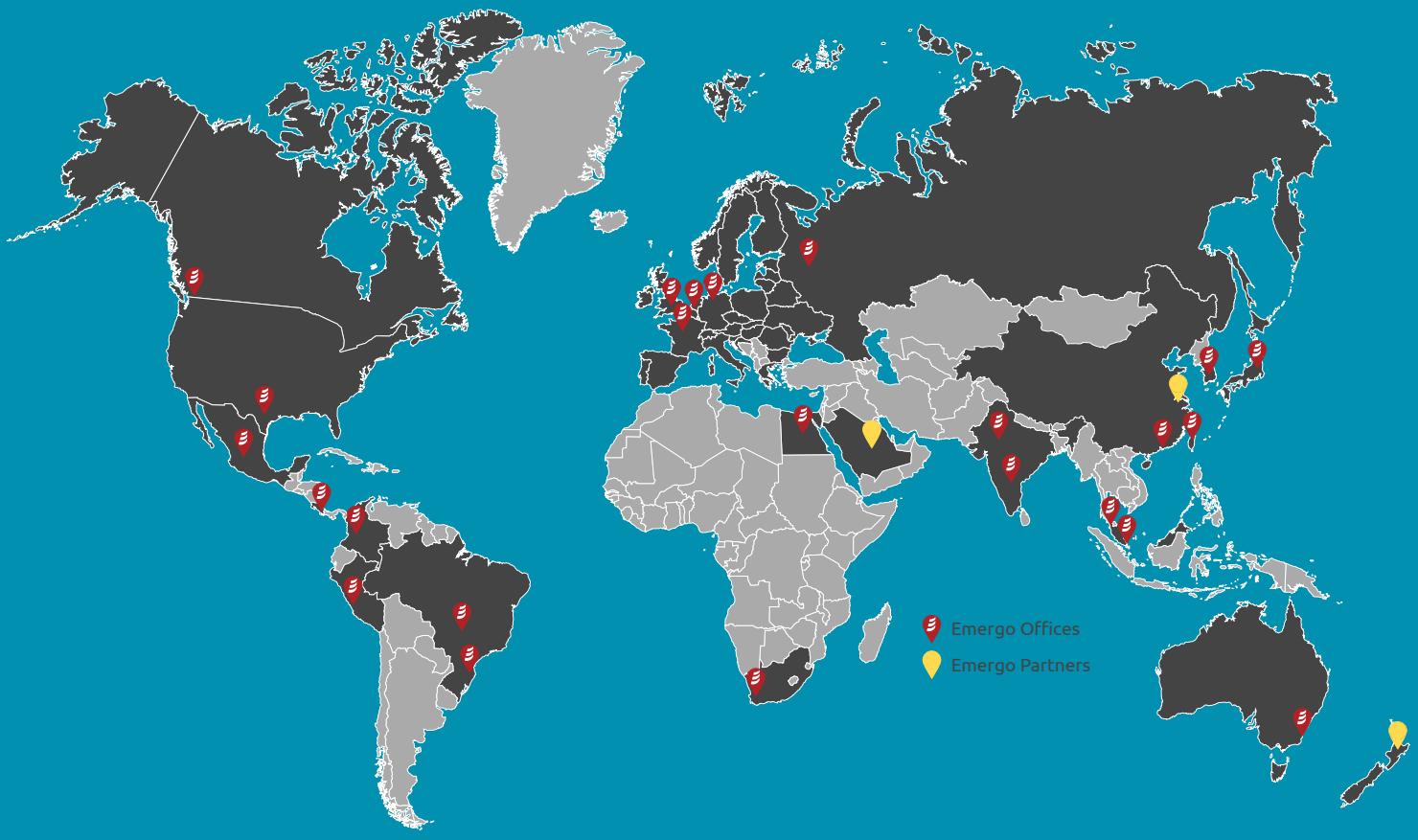
We have dedicated teams in North America, Europe and Asia, and they all use the same project management platform. Our teams work closely with our consultants and provide updates so you know the expected time to completion, and the remaining budget. Plus, we often allocate a "fresh set of eyes" to review important deliverables for quality, accuracy and completeness before they are sent to you.

We carefully track the time spent to complete each client project and use years of historical data to estimate the cost of new projects. Barring unforeseen complications or an expansion of scope, most projects are completed within the original budget.

From New York to Tokyo, Emergo can help you expand into major medical device markets worldwide.

Emergo Gives You Access to 90% of the Global Device and IVD Market

Expanding internationally? We are ready to grow with you. Understanding how to efficiently achieve compliance with overlapping international regulations is critical. There is no need to hire consulting firms with loose affiliations in other countries. There is no need to rely on local distributors or hire consulting firms with loose affiliations in other countries. Our global offices can handle all of your regulatory needs.



Emergo has offices and partners available to serve you worldwide:

Sydney
AUSTRALIA

Brasília & São Paulo
BRAZIL

Surrey
CANADA

Shanghai
CHINA

Bogotá
COLOMBIA

San José
COSTA RICA

Cairo
EGYPT

Paris
FRANCE

Hamburg
GERMANY

Hong Kong
HONG KONG

Delhi & Secunderabad
INDIA

Haifa
ISRAEL

Tokyo
JAPAN

Kuala Lumpur
MALAYSIA

Mexico City
MEXICO

The Hague
THE NETHERLANDS

Auckland
NEW ZEALAND

Lima
PERU

Moscow
RUSSIA

Riyadh
SAUDI ARABIA

Singapore
SINGAPORE

Cape Town
SOUTH AFRICA

Seoul
SOUTH KOREA

Taipei
TAIWAN

Sheffield
UNITED KINGDOM

Austin
UNITED STATES

AUSTRALIA

- TGA Sponsor representation
- ARTG listing/registration
- Prostheses List consulting
- TGA vigilance reporting

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BRAZIL

- ANVISA device registration
- Brazil Registration Holder
- BGMP QMS compliance
- Classification assessment

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CANADA

- Medical Device License (MDL)
- Establishment License (MDEL)
- ISO 13485/MDSAP compliance
- Risk management consulting
- Adverse event reporting

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CHINA

- CFDA device/IVD registration
- Clinical/testing assessment
- China regulatory strategy
- CFDA advisory meetings

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COLOMBIA

- INVIMA device registration
- Legal Representative
- Classification assessment
- Regulatory pathway report

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COSTA RICA

- Device/IVD registration
- Registration Holder
- Classification assessment
- Regulatory pathway report

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EGYPT

- CAPA device registration
- Certificate of Free Sale
- Classification assessment
- Regulatory pathway report

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EUROPE

- CE Marking certification
- MDR/IVDR transition
- ISO 13485:2016 compliance
- EU Authorized Representative
- Clinical Evaluation Reports

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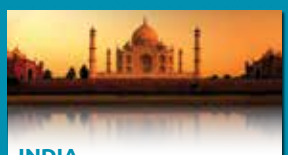

INDIA

- CDSCO registration
- India Authorized Agent
- Classification assessment
- Regulatory pathway report

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ISRAEL

- AMAR registration
- Israel Registration Holder
- Certificate of Free Sale
- Regulatory pathway report

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JAPAN

- PMDA device/IVD registration
- Ordinance 169 compliance
- Foreign Mfr. Registration (FMR)
- Japan GCP compliance

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MALAYSIA

- MDA device/IVD registration
- Authorized Representative
- MDA regulatory strategy
- Regulatory pathway report

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MEXICO

- COFEPRIS device registration
- Mexico Registration Holder
- Grouping/classification
- COFEPRIS vigilance reporting

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NEW ZEALAND

- MedSafe device registration
- New Zealand Sponsor
- Regulatory strategy
- Regulatory pathway report

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PERU

- DIGEMID registration
- Peru Registration Holder
- Classification assessment
- Regulatory pathway report

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RUSSIA

- Device/IVD registration
- Authorized Representative
- Testing needs assessment
- Roszdravnadzor strategy

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SAUDI ARABIA

- SFDA device registration
- Authorized Representative
- KSA regulatory strategy
- Certificate of Free Sale

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SINGAPORE

- Classification assessment
- HSA device registration
- Singapore Registrant
- Vigilance reporting

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SOUTH AFRICA

- Electrical device registration
- Market overview report
- Product assessment
- Wireless compliance

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SOUTH KOREA

- MFDS device registration
- KGMP QMS compliance
- Korea License Holder
- Vigilance consulting

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TAIWAN

- TFDA device registration
- Taiwan Agent representation
- Vigilance reporting
- QSD compliance

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UNITED STATES

- FDA 510(k) preparation
- QSR implementation & audits
- US Agent representation
- ISO 14971 risk management
- MDR adverse event reporting

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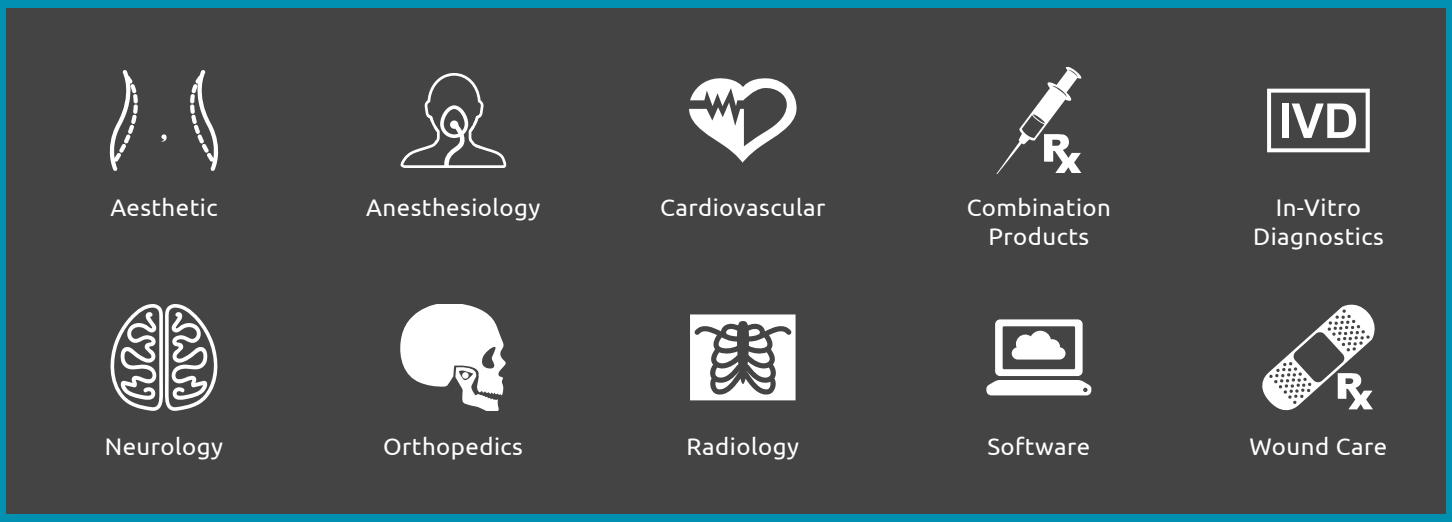
Emergo is the leading medical device regulatory consultancy with clients in 60 countries

100% Focused on Medical Device and IVD Compliance

Emergo serves more than 2,800 medical device and IVD clients producing a wide variety of medical devices and IVDs. Because we have such a large consulting team, chances are good that we have experience with your specific device or the category. We have proven expertise in these major categories:



3 more reasons to choose Emergo

1. **We're ready to grow with you**
   Emergo can help you access 95% of the global medical device market through our worldwide network of offices. When you're ready to expand, we are too.

2. **We offer you ongoing flexibility**
   If you choose Emergo as your independent regulatory representative in a specific market, you won't be tied to a specific distributor. More than 2000 companies worldwide trust us as their representative.

3. **We respect intellectual property**
   Do you trust your distributor with your proprietary technical information? Emergo is not in the business of making or selling devices and has nothing to gain from sharing your sensitive data.

NEW! Ask us about services for:

- Biocompatibility testing
- Cybersecurity and UL 2900
- Human Factors Engineering (HFE)
- Online device registration tracking
- Mechanical/performance testing
- Regulatory change monitoring

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ISO 13485 EMERGO Quality Since 1997 QMS Certified