CSA GROUP™

GUIDE

Healthcare Startups and SMBs: Electromedical Device Certification for Global Market Access





Seize global market opportunities by leveraging the knowledge and networks of international certification experts.

Overview of CSA Group

At CSA Group, we understand that efficient, reliable, and predictable service is essential to your healthcare startup, and your level of confidence in the service that we deliver is essential to us. Moreover, we understand that obtaining certification to access global markets can be a costly and lengthy endeavor, considering the resource constraints faced by many startups and small-medium sized businesses (SMBs).

However, the need to navigate intricate regulatory demands for global market entry is not exclusive to large, multi-site corporations. In an ever-evolving and globally competitive business environment, healthcare startups and SMBs have been seeking certification, as organizations have recognized its benefits. For instance, some view securing entry into global healthcare markets as a competitive advantage or the next evolutionary step for their small business. While accessing global markets offers numerous benefits for businesses of all sizes, it is vital to work with a Certification Body with expertise in the healthcare industry and who is familiar with supporting small businesses.

CSA Group is an internationally recognized Certification Body with a team of experts that possess a deep understanding of the intricate regulatory landscape. We can help you take full advantage of today's global economy, serving as a centralized service provider to help you navigate regional and international requirements to access target markets and achieve credibility on a global scale. Accredited as a National Certification Body (NCB) through the IECEE CB Scheme and recognized by Authorities Having Jurisdiction (AHJs), we offer radio and electrical safety testing and certification against key international standards, such as the IEC 60601/ISO 80601 series, IEC 61010 series, and more, to help bring your electromedical devices to market.



70
Countries

Helping you access 70 markets for your medical products, including North America, China, Japan, and the EU.

3,000
Organizations Worldwide

Helping manufacturers around the world with testing & certification needs.

100+
Years of experience

Rely on an internationally recognized organization with over a century of experience.

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International Certification

For healthcare startups and SMBs, CSA Group acts as a strategic service provider, offering crucial support in navigating the dynamic landscape of product certification. We understand the unique challenges faced by startups, and our international expertise, coupled with strong collaborations with over 200 global regulatory bodies, enables us to guide you through the intricate compliance requirements of various countries. Whether you are managing complex supply chains or seeking assistance with product specifications, supplier selection, shipping inspections, or audits, our experienced team is here to help. We can help with your focus on maintaining compliance, confirming performance, and enhancing security, all while facilitating your path to market entry.

Our international certification services provide:

- Predictable project delivery timelines.
- Seamless integration with your healthcare product development cycle.
- Local multilingual service capability.
- Renewal notification and processing.
- Update notifications of changes to national standards and regulations.



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Global Market Access Service

In an increasingly competitive and globalized business landscape, we recognize that failing to capitalize on opportunities beyond your borders might impede the growth of your business, proving especially detrimental for startups and SMBs.

You can seize the opportunities of global markets by leveraging our network of international certification experts. Our Global Market Access (GMA) team is equipped to help you take advantage of today's global economy, supporting you as a centralized service provider to help you navigate local and international requirements and access target markets.

Understanding CSA Group's GMA Service

We have eight GMA offices located throughout North America, Europe, and Asia, with laboratories and affiliates in over 100 countries. Our teams understand the challenges of accessing global target markets, backed by decades of international experience. Our GMA team helps identify the applicable requirements for each of your target markets and provides a testing and certification plan to help you gain access to those markets. Our team can also work with third-party organizations, other certification bodies, and authorities to facilitate overseas certification on behalf of healthcare startups and SMBs.



Here is how our GMA team can support you:

- **Step-by-Step Support:** Navigating the international regulatory environment is daunting, even for large corporations. That is why our team provides guidance at each stage — as early as the product design phase through to successful market entry.
- **Personalized Solutions:** We approach your business as if it were our own, prioritizing your business objectives and strategic goals. This allows us to help you develop a strategic plan to access crucial global markets within your specified timelines and budget constraints.
- **International Expertise:** Our GMA team can help you identify new opportunities and provide you with an extensive overview of the regulatory landscape for each market you wish to enter.
- **Vigilance with Confidence:** We understand that your global target markets have trust in the marks that exist within their own borders, so we help ensure that your products are certified according to the latest country requirements.
- **A Centralized Solution:** Our GMA teams can plan a testing strategy, integrate requirements throughout your product lifecycle, and help confirm your ongoing compliance.
- **Local Knowledge:** Our experience with local markets and processes translates into speed-to-market efficiencies.

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The Certification Process

For healthcare startups and SMBs seeking entry into markets around the world, here are some key questions to consider when planning to sell your electromedical devices abroad:

- Does the product have approvals from the International Medical Device Regulators Forum (IMDRF), including country approval, Country of Origin approval, and ISO 13485 certification?
- What is the equipment classification under current approvals?
- Is the intended purpose clear, and is the Instruction for Use (IFU) available in the target market's local languages?
- Are product technical files, including risk management files, clinical evaluation reports, and IEC 60601 series test reports available?
- Is a local representative available in the target market?
- Where is the manufacturing facility located?
- Does the device incorporate wireless technology, and if so, what type of wireless technology is used?

Frequently Asked Questions:

Here are a few commonly asked questions that our GMA team receives from healthcare startups and SMBs looking to bring their radio/ wireless medical device to global markets:

- **Do I need to certify my product if the wireless module has already been approved?**

  In some countries, you may need to obtain new approval for the end device incorporating the approved wireless module.

- **Do I need to retest my product when integrating an already tested wireless module?**

  You need to do a retesting of some parameters with the module added into the host device. During this retesting, it is important to make sure the limits are still the same and the end device still complies with required regulations.

- **If a new approval is necessary for a wireless-enabled medical device, do I need any documents from the module manufacturer?**

  In addition to the integration test report, you may need to submit test reports and technical documentation specific to the module for review and approval.



The **International Medical Device Regulators Forum (IMDRF)** is composed of medical device regulators from around the world who have voluntarily come together to harmonize regulatory requirements for medical products and devices that vary among countries.

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Let's work together

csagroup.org

Put CSA Group's industry-leading knowledge and experience to work for you.

+1 866 797 4272

client.services@csagroup.org

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