

Alps Electric EMS Achieves ISO 13485 Certification, Strengthening Its Position in Medical Technology Manufacturing

Millstreet, Co. Cork, Ireland – Alps Electric EMS has achieved ISO 13485 certification, marking an important milestone in the company's continued growth as a trusted high-reliability manufacturing partner and strengthening its position within Ireland's thriving medical technology sector.

The achievement follows an accelerated company-wide initiative that brought together colleagues from across quality, engineering, production, supply chain, administration and leadership. While organisations are often advised to allow a year or more to prepare for ISO 13485 certification, Alps Electric EMS successfully completed the process in a matter of weeks, demonstrating the collaborative culture, commitment and manufacturing disciplines already embedded throughout the business.



ISO 13485 is the internationally recognised standard for quality management systems within the medical device industry, demonstrating an organisation's ability to consistently meet customer and regulatory requirements applicable to medical devices and related services. The certification supports Alps Electric EMS' manufacture of medical

devices and reflects the company's commitment to robust quality systems, full traceability, documentation and risk management.

While the certification itself was achieved in just a few weeks, it was only possible because it built upon decades of investment in manufacturing excellence. For nearly 40 years, Alps Electric EMS has developed the processes, systems, quality culture and operational disciplines required to manufacture products where consistency, precision and reliability are essential. ISO 13485 does not represent the start of that journey; rather, it formally recognises the high standards that have long existed throughout the organisation.

Operating from its manufacturing facility in Millstreet, County Cork, Alps Electric EMS has established a reputation for supporting OEMs operating in demanding sectors where product quality cannot be compromised. The company consistently achieves rigorous manufacturing standards applied across every stage of production.

As part of the global Alps Alpine Group, Alps Electric EMS combines international expertise with local manufacturing excellence through its vertically integrated **EMS+** model. By bringing SMT PCB assembly, injection moulding, painting and laser etching, automation, testing, assembly, supply chain management and fulfilment together under one roof, the company provides customers with a simplified manufacturing partner capable of supporting increasingly complex products throughout their lifecycle.



Medical technology represents a natural progression for the business. The disciplines required within regulated medical manufacturing closely align with the standards Alps Electric EMS has been applying for many years across high-reliability manufacturing environments.

John Foley, Managing Director of Alps Electric EMS, commented:

"Medical technology is a natural fit for our business. The disciplines, quality systems and attention to detail required by the medical sector closely align with the standards we have been applying throughout our operations for many years."

"What makes me most proud is how our people came together to achieve this certification. We were told the process could take a year or more. Our team decided otherwise. Everybody understood the importance of what we were trying to achieve, worked together and delivered something extraordinary for the future of the business."



Ireland is recognised as one of the world's leading medical technology hubs, home to many of the global industry's largest manufacturers and an expanding ecosystem of innovative healthcare companies. As the sector continues to grow, OEMs increasingly require manufacturing partners that combine technical expertise with robust quality systems, regulatory understanding and the ability to scale production with confidence.

For Alps Electric EMS, ISO 13485 provides an important platform for supporting both established medical device manufacturers and emerging innovators. For customers, it offers additional confidence that the company has the governance, traceability, manufacturing disciplines and quality management systems required to support products where patient safety, compliance and product performance are paramount.

Thomas O'Leary, Senior Quality Manager at Alps Electric EMS, added:

"ISO 13485 is far more than a certificate. It reflects a culture of quality that runs throughout the organisation. Achieving this standard required dedication, professionalism and teamwork from colleagues across the entire business."

"Quality is not owned by one department. It is everyone's responsibility. The certification gives medical device companies confidence that they are working with a manufacturing partner that understands the importance of quality, traceability, documentation and risk management throughout the medical device lifecycle."

Customers visiting the Millstreet facility are often surprised by the breadth of manufacturing capabilities available within a single location. Unlike many EMS providers, Alps Electric EMS' EMS+ approach brings engineering, automation development, injection moulding, electronics manufacturing, testing, assembly and supply chain expertise together in one integrated environment, improving collaboration, simplifying communication and enhancing traceability throughout the manufacturing process.

Looking ahead, the company sees ISO 13485 not as the destination, but as the next chapter in its continued growth within the medical technology sector.

"At the heart of this achievement are our people," continued Foley. "Their dedication, expertise and commitment to doing things the right way made this possible. We've invested for many years in creating the right environment, the right processes and the right culture to support customers operating in highly regulated industries. ISO 13485 validates that commitment and gives OEMs confidence that they are working with a partner capable of delivering the quality, consistency and long-term support their products demand."

Alps Electric EMS will showcase its ISO 13485-certified manufacturing capabilities and EMS+ approach at **Medical Technology Ireland**, taking place at Galway Racecourse on **23–24 September 2026**.



NSAI

**Certificate of Registration
of Quality Management System
to ISO 13485:2016**

The National Standards Authority of Ireland certifies that:

**Alps Electric (Ireland) Ltd.
Clara Road,
Millstreet Town
Co. Cork,
P51 XC56, Ireland**

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

**Contract Manufacturer of Components and Subassemblies
for use in General Active Medical Devices.**

Additional sites covered under this multi-site certification are listed on the Annex
(File No. CM19.8806)

Patricia Buckle Miller
Approved by
Patricia Buckle Miller
Certification Manager

Certificate Number: CM19.8806
Certification Granted: 30 June 2026
Effective Date: 30 June 2026
Expiry Date: 29 June 2029



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About Alps Electric EMS

Alps Electric EMS is a leading provider of high-reliability Electronic Manufacturing Services based in Millstreet, County Cork, Ireland. Part of the global Alps Alpine Group,

the company delivers vertically integrated manufacturing solutions including SMT PCB assembly, injection moulding, painting and laser etching, automation, testing, assembly, supply chain management and fulfilment. Through its EMS+ approach, Alps Electric EMS supports OEMs from prototype through to full production, helping innovative companies bring increasingly complex products to market with confidence.

Learn more: <https://alpselectric-ems.com/>

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