

Hallmark Nameplate- Press Release

Hallmark Nameplate Attains ISO 13485 Certification

At Hallmark Nameplate, our commitment to quality is what sets us apart. We are proud to announce that we have achieved certification to ISO 13485. **This certification is another way we are making constant strides to provide our customers with the best and most up to date products and services that they need.**

The ISO 13485 Certification is a major accomplishment for Hallmark Nameplate and will allow us to be involved in the production and service of medical devices and related services. Our products will be able to provide great services for extremely vital causes that we care about, as the devices we will be working with are medical instruments, machines or in vitro reagents, that are intended for use in the diagnosis, prevention, and treatment of diseases or other medical conditions.

Adding the 13485 Certification is part of Hallmark Nameplate's commitment to staying abreast of global requirements in our areas of expertise. The standard includes a wide variety of medical devices and equipment, including dentistry, cardiology, and life support.

ISO 13485 is based on the requirements of ISO 9001 and as the same structure of clauses. The ISO 13485 standard, medical devices- quality management systems- requirements for regulatory purposes, is the basis for regulatory compliance in local and most export markets, and having certification demonstrates Hallmark Nameplate's commitment to meeting customer requirements.

Hallmark Nameplate applied for ISO 13485 in order to manufacture and supply medical devices and components. Some of the specific requirements for manufacture, installation, and servicing requires a validation of process, compliance with statutory and regulatory requirements, effective product traceability and recall systems, and implementation of a quality management system with several enhancements.

The entire certification process involves three simple steps. The first is applying for the certification, followed by a basis audit to check whether the organization is in a state of readiness. That includes confirming that the quality manual conforms to the requirements of the ISO 13485, confirming the scope of certification including any justifiable exclusions, checking legislative compliance, production of a report that identifies any non-compliance or potential for non-compliance, an action plan, and production of an assessment plan. The final step involves a visit in order to document the entire system.

It is important to all of us here at Hallmark Nameplate that our customers are aware of how seriously we take our standards. No matter the product, we want it to be the best and most reliable for all of our clients. We are extremely proud that we are able to extend our variety of

products into the medical field, and are excited to see what great things will come of this certification.

When it comes to making quality products that our customers trust, our standards are everything. Our company is certified to ISO 9001, registered to ITAR and UL/CSA recognized on many substrates and adhesives. Our goal is to continue to become certified in areas that will enhance our company and better serve our customers.

Some of the benefits of achieving ISO 13485 Certification include the emphasis of meeting regulatory as well as customer requirements, risk management, and maintaining effective processes. It is also designed to produce a management system that facilitates compliance to the requirements of customers and global regulators.

This certification will give Hallmark Nameplate the ability to communicate the exact quality of products that will in turn, allow customers to recognize the products and services that are reliable and trustworthy. The standard requirement not only addresses the regulatory requirements applicable for medical device realization but also for device specific and customer specific requirements that have potential adverse impact and risk on the product.

What this certification will do is reduce the production loss rate, reduce operational costs, increase effectiveness across the entire Hallmark Nameplate organization, and reassure the customer's trust. Some of the additional requirements relate to process controls, special processes, traceability, record retention, and regulatory actions. It also emphasizes the cleanliness in the production area, increasing efficiency and safety in the workplace.

Hallmark Nameplate takes its credibility very seriously, and the certifications we have with these groups is yet another indicator of our focus on value and customer satisfaction. We want our customers to feel confident entrusting us to handle any and all projects, and the results will certainly speak for themselves.