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Not only is ISO 13485 Certification a validation of the high standards that Sisu Global follows in our quality procedures to ensure a safe product, but it has also been critical in our expansion. ISO 13485 is recognized as a global standard and being certified with this standard, has opened up new global markets for our novel autotransfusion device, Hemafuse.

- Carolyn Yarina, CEO & Co-founder of Sisu Global Health



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About Sisu Global Health

Sisu Global is an American ISO 13485 certified company that designs medical devices for emerging markets. Since its beginning in 2014, Sisu Global's mission is focused on increasing blood access by enabling clinicians to use a patient's own blood to save them with a medical device that has the ability to operate anywhere there is a surgeon.

Sisu Global has 3 issued patents with the U.S., international coverage, and has been recognized by the US Patent Office with a Patent for Humanity. They are also currently in the process of expanding sales from Kenya and Ghana into new geographies.



Why did you choose to get certified against ISO 13485?

ISO 13485 allows Sisu Global to provide safe and effective products to emerging markets, globally. It has helped us meet an international standard, assisting in the expansion of our product within Kenya and Ghana by meeting regulatory requirements, and helped us establish a quality management system for medical device development.

What are the main benefits of your company after the implementation and certification against ISO 13485?

ISO 13485:2016 has given Sisu Global access to new markets. As a start-up company, this implementation and certification against ISO 13485:2016 has helped us ensure our framework to design and develop medical devices that consistently meet customer requirements across the life-cycle of our devices. The certification has supported Sisu Global in expanding into emerging markets with life-saving emergency medical devices such as the Hemafuse.

About your experience with PECB MS

“Working with PECB MS was an overall positive experience – they provided flexibility of remote audit during the COVID-19 pandemic. Our auditor was skilled, competent, and personable.”





About PECB MS

PECB MS is specialized in the certification of management systems on a wide range of international standards. As a global provider of audit and certification services, PECB MS offers its expertise on multiple fields, including but not limited to Information Security, Quality Management, Business Continuity, Service Management, Health, Safety and Environmental Management. PECB MS provides certification services in accordance with ISO/IEC 17021 and ISO/IEC 17065.

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