

UK medical mattress manufacturer realizes sweet dreams with ISO certification

CASE STUDY





Squirrel Medical, founded in 2003, designs and manufactures medical devices that enhance circulation and vascular health.

The Cornwall-based company's flagship product is an active alternating pressure mattress that uses a perpetual massaging effect to improve blood flow significantly. This directly addresses pressure ulcers and many circulation-related disorders. Scientific validation and a patented system underpin Squirrel's reputation for clinically effective, regulation-compliant innovation.

Product development

Squirrel Medical's mission began when the co-founders, Gary and his brother Rick Baker, launched a small-scale study after meeting with clinicians, elderly patients and Dr Rodney Gush, Senior Applications Scientist at Moor Instruments, the global leader in developing tissue blood flow and oxygen assessment products.

Utilizing Moor Instruments provided unique insights into the effects different pressures have on endothelial function, which is vital as endothelial dysfunction contributes to cardiovascular disease.

One of the main approaches for preventing and treating cardiovascular disease is to improve endothelial function through physical exercise. However, this becomes more difficult due to the effects of ageing. Gary and Rick realized it might be possible to supplement or replace exercise by simply sleeping on a specially designed mattress. The resulting product – Vestims® (the Vascular Endothelial Stimulation System).

The Vestims active mattress uses patented pneumatic air chambers and a medical-grade algorithm to sequentially alternate pressure. The system is clinically proven to improve vascular function – documented in a PubMed-indexed study showing a +197% improvement in endothelial function. Other observed benefits included a 336% increase in resting blood flow, better thermoregulation, reduced joint pain and improved sleep. A Barchester Healthcare study, presented at EPUAP 2024 in Lausanne, showed a 66% reduction in pressure injuries and a 75% improvement in general health for critically ill patients.

Combining unique features, technologies and patents, Vestims became available in two formats:

1. 15cm version – firmer, promotes self-repositioning, fully compatible with UK safety rail regulations. The system includes proprietary pneumatic sequencing and is patented (2012). Its design mitigates falls (a leading category in mattress-related adverse events) while enhancing safety, comfort and circulation
2. 18cm version – softer, for highly dependent patients with high-side hospital bed compatibility

Clinical Research Study

Gary has completed a three-year Master's degree, specializing in the effects that mattresses have on blood flow and health, at Plymouth Marjon University. His accompanying, widely published research paper was Vascular Endothelial Function is Improved After Active Mattress Use. The study is based on 10 healthy participants (4 males, aged 52.7±8.5 years, 6 females, aged 51.8±17.5 years)

and concluded that active mattress for 8 weeks led to significant improvements in resting blood flow (+336%) and endothelial function (+197%). This is crucial because everything humans do is linked to blood flow, and endothelial dysfunction is the precursor to cardiovascular disease.

Skin temperature is also improved by 3.5°C at the toes while remaining stable throughout the body. This is important because many people suffer from painfully cold feet, even at room temperature, one reason why some homes for elderly people are maintained at such high temperatures.

The participants, who had a 76kg mean average weight, experienced a significant increase in muscle or fat-free mass following the 8-week study. This is interesting and important because elderly people can progressively lose muscle mass, which can lead to frailty and balance issues, frequently leading to falls and further health problems. Using the Vestims mattress could increase muscle fat-free mass in the elderly.

Blood pressure approached statistical significance with a drop from 120/77 to 115/75. This, alongside the other parameters, is also linked to improvements in endothelial function.

Many participants also reported feeling better and free from morning stiffness and joint pain. It is not only the elderly, however, who can benefit from the Vestims mattress. It also has significant pros for users of any age and state of health due to its ability to simulate exercise during sleep.

Why pursue ISO 13485 certification?

The MHRA has confirmed that active mattresses are a Class IIa medical device under UK Medical Device Regulation (MDR) 2002, thus requiring third-party conformity assessment. Squirrel Medical wanted to meet these standards by achieving ISO 13485 (medical devices quality management systems) certification with SGS Notified Body assessment. This was vital for legal market access and patient safety. Given the black market in non-compliant devices, verified certification (SGS Certificate & MHRA Certificate of Free Sale) is essential to demonstrate legality and quality.

Class IIa mandates independent oversight for fire risk, toxicity, electrocution and clinical efficacy. Given the vulnerability of patients relying on these devices, conducting rigorous assessments is a moral obligation and regulatory requirement.

“The SGS team, including the initial customer contact, internal lead auditor trainers and two respective auditors, had an extremely high level of competence, meaning they were always clear in their communication and able to point to the most effective solution.”

The steep transition from self-declaration to full UK MDR 2002 Class IIa certification posed early challenges. SGS, as a leading Notified Body, has a duty of care to abandon audits if a company's systems or technical files are inadequate. Gary and Rick spent years training staff to ensure evidence-based compliance, not just documentation.

Squirrel Medical conducted extensive internal audits and staff training. Parallel to this, Gary undertook a three-year Master's research program at the University of St Mark & St. John, generating clinical data on the long-term physiological benefits of active mattresses. Findings published in the Journal of Wound Care and listed in PubMed were key to building the 180-page Clinical Evaluation Report, a cornerstone of SGS audit success.

Implementing ISO 13485

Gary recalls SGS's support during the initial inquiry stage in reviewing current processes and defining requirements. He estimates that tens of thousands of pounds were saved by restructuring the business before proceeding with the application.

Gary and his colleagues also attended the two-day, online SGS internal auditor course. He recalls: *“The course leader was incredibly knowledgeable in his subject, which meant he could answer any question in a very clear and easy-to-understand manner. The course was actually fun and structured in a sensible gradient, so, at every stage, you had the sense that you were in control, that you were developing in line with expectations.”*

The internal auditing procedure is a crucial part of ISO 13485 because it allows all staff involved with the project to review every procedure and process, even those relating to other departments. This means that the general knowledge relating to ISO 13485 is group-wide – rather than being retained by the individual – enabling the whole team to move the business forward. The internal audit is an important part of internal training, ensuring that the policies and procedures are always up to date, fit for purpose (the business may change its policy or strategy) and in line with regulatory requirements. The company was given ample notice of the audit process timetable and topics that would be covered, and in which order.

This enabled sufficient time and direction to ensure that the quality management system would be sufficient for the stage-one audit, a process that involved some 40 hours of preparation.

The stage-one audit revealed several minor nonconformances, which were detailed thoroughly in a written document, with a verbal explanation of why these were an issue. The final audit stage was conducted in person by an SGS auditor, again receiving praise from Gary for his interpersonal skills and knowledge of the medical device industry, regulations and the mattress itself. Following notification and remediation of one further minor non-conformance, ISO 13485 certification was awarded.

Why SGS?

Squirrel Medical's research partner, Moor Instruments, is certified against Directive 93/42/EEC for several medical devices, with SGS as the Notified Body.

In addition, Squirrel Medical outsources the physical manufacture of its products. This critical supplier is also audited by SGS to ISO 13485. It is these associations, combined with SGS's reputation and position as the world's leading testing, inspection and certification company, that made it the natural partner of choice.

How has certification impacted market access, sales and reputation?

MHRA states that it is illegal to market non-compliant medical devices in the UK. Despite over 100 suppliers, only 11 companies were correctly registered for Class IIa active mattresses. Squirrel Medical is among the few, and possibly the only, companies that have publicly demonstrated UK MDR 2002 compliance. This distinction has significantly enhanced trust within hospitals and care homes.

The certification ensures that Squirrel Medical products are future-proof beyond the MDD's 2028 deadline. As a result, interest has surged from both NHS procurement teams and private investors. Certification also reassures care providers that they are fulfilling their legal duty of care by purchasing demonstrably compliant equipment.

Gary adds: *"ISO 13485 is a quality management system*

that really works – it's brilliant. I admit we were initially skeptical, but it has been well thought out by experts and has improved our processes and productivity."

"We are extremely satisfied with SGS for their integrity and global coordination. Their rigorous audits pushed us to world-class standards in quality assurance and compliance. Certification has certainly fulfilled the company's original objective for attaining it: the ability to sell into the care home sector. However, the NHS has also specified the standard for hospital applications, opening up exciting new direct-selling opportunities for Squirrel Medical."

Plans for future product improvements or new product launches

Having clinically validated vascular health benefits, Squirrel Medical will now expand into the domestic wellness market, offering Class IIa mattresses to consumers seeking better sleep, circulation and comfort.

Investor interest has driven plans for OEM partnerships, dual-branding and global distributor support, offering fast-access, off-the-shelf certified mattresses under UK MDR 2002.

Client testimonials

"The introduction of a fully automatic dynamic air support surface in a long-term care setting significantly improved pressure ulcer management... 75% of residents exhibited healing or stability. Compliance with IEC 60601-2-52 bed rail regulations was maintained, and residents reported high comfort levels."

– Barchester Healthcare, Poster Study, Wounds, UK 2024

Advice to organizations considering ISO 13485 certification

Gary is happy to advise other small businesses considering certification. He recommends:

"Engaging a consultant with proven experience, rather than the false economy of looking for a low-cost, templated solution on the internet."

Pursuing Class IIa certification is a strategic investment, not just a regulatory checkbox. It can cost £500,000+ and take years, but success delivers market leadership. Failure after years would be disastrous, success demands the best team, systems and auditors."

If your focus is active mattresses, start the certification journey now. If you're a distributor, consider dual branding with a fully compliant UK manufacturer like Squirrel Medical. We handle regulatory complexity while allowing you to lead with your brand."

Finally, he recommends SGS's two-day internal auditor course for being invaluable in developing the skills to perform internal audits of ISO 13485 and other quality management systems. *"I would recommend that all of the procedures are audited internally before your stage-one SGS audit, which may mean a gap of several months between the application and the stage-one audit, but one that is worth it."*

Working with SGS

On working with SGS, Gary adds: *"They were very helpful, leading us through the process and explaining any issues most easily and effectively. We have pulled together our respective work processes, resulting in efficiency and productivity improvements."*

He estimates certification as having a net benefit – rather than a net cost – with a return on investment for Squirrel Medical in just 12 months.

He concludes: *"I have no hesitation in recommending SGS to anybody looking to seek ISO 13485 certification and UKCA marking and have, indeed, done so."*

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and setting you apart in the competitive landscape.

As a world leader in assessment, auditing and certification, our global network of experts offers comprehensive support for regulations like the [EU MDR \(2017/745\)](#) and [IVDR \(2017/746\)](#).

With specialists worldwide, we ensure your compliance with diverse international standards. Our services, spanning MDR and IVDR, CE marking, [UKCA](#), [ISO 13485](#) and [MDSAP](#), are delivered by our EU Notified Bodies and UK Approved Body, ensuring robust, transparent assessments and a competitive edge through regulatory trust.

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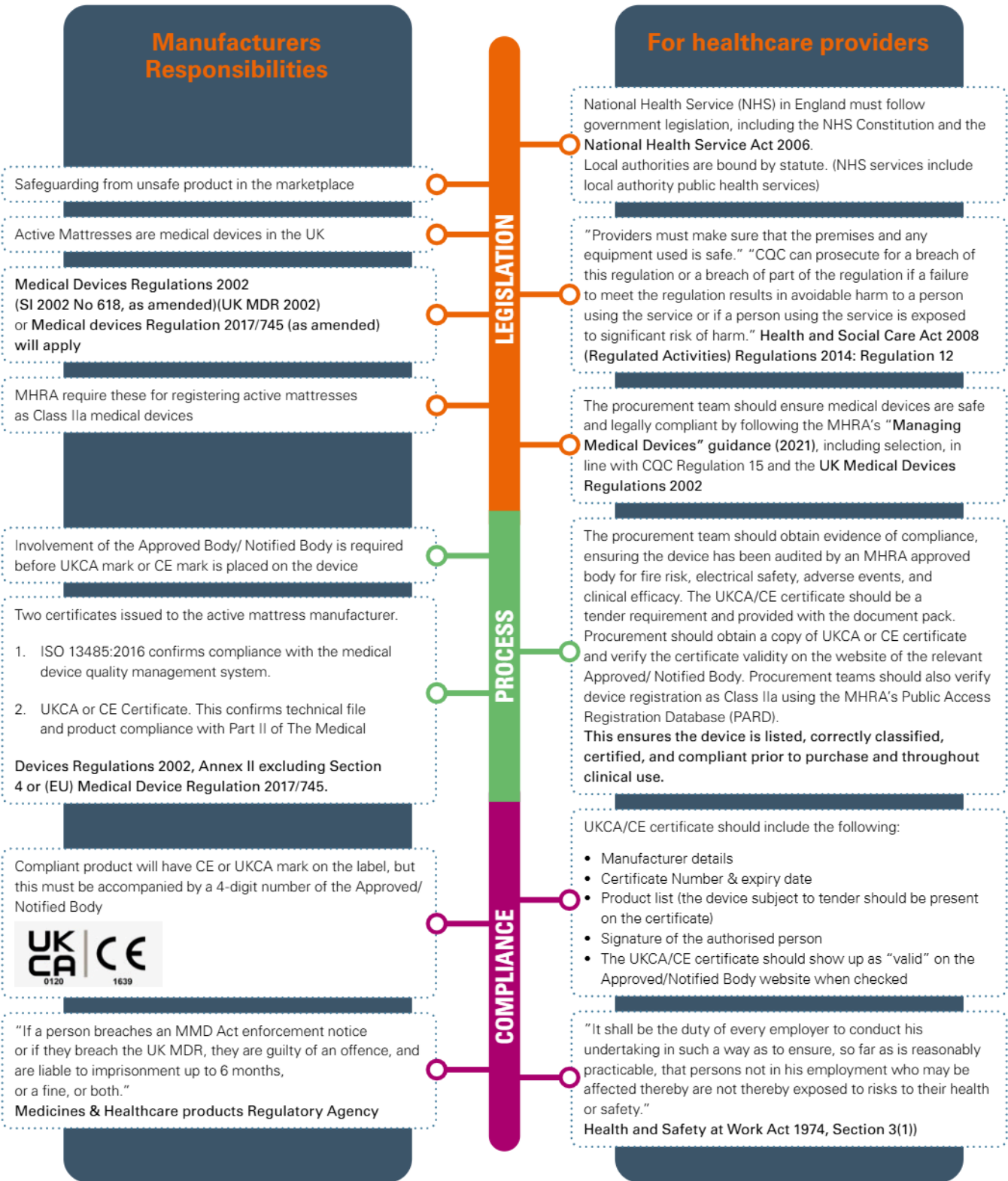
About SGS

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Compliance roadmap for active alternating mattresses & cushions

Legal Responsibilities for Manufacturers and Healthcare Providers in the UK

A structured guide to ensure safety, regulatory compliance, and procurement integrity under the UK medical Devices Regulations, NHS Constitution, and Health and Social Care Act 2008.



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