

# ISO Certification for Cornwall medical mattress manufacturer

CASE STUDY

**SGS**



**Squirrel Medical specialises in the design, manufacture and sales of a range of healthcare mattresses. Established in 2003, the company is based in Torpoint, Cornwall, has five employees and is headed by founder and Sleep Health Scientist Gary Baker.**

Baker's motives for setting up the company with his brother Rick were both commercial and altruistic. They had become aware of the serious health consequences of inadequate mattresses for both care home residents and people in their own homes confined to their beds for long periods.

This led the brothers to embark on a research programme with the aim of providing a low-cost but highly effective mattress that would improve blood

flow and other aspects of the vascular endothelial function. The endothelium is the thin lining on the inside of the heart and blood vessels. Endothelial cells release substances that control vascular relaxation and contraction as well as enzymes that control immune function, blood clotting and platelet adhesion.

### Scientifically proven to enhance muscle (fat free) mass.

8 weeks use of a VeSTIMs® mattress lead to a +336% increase in blood flow, +197% increase in endothelial function and a +0.52 kg increase in muscle (fat free) mass.



### Scientifically Proven to Enhance Blood flow & Health

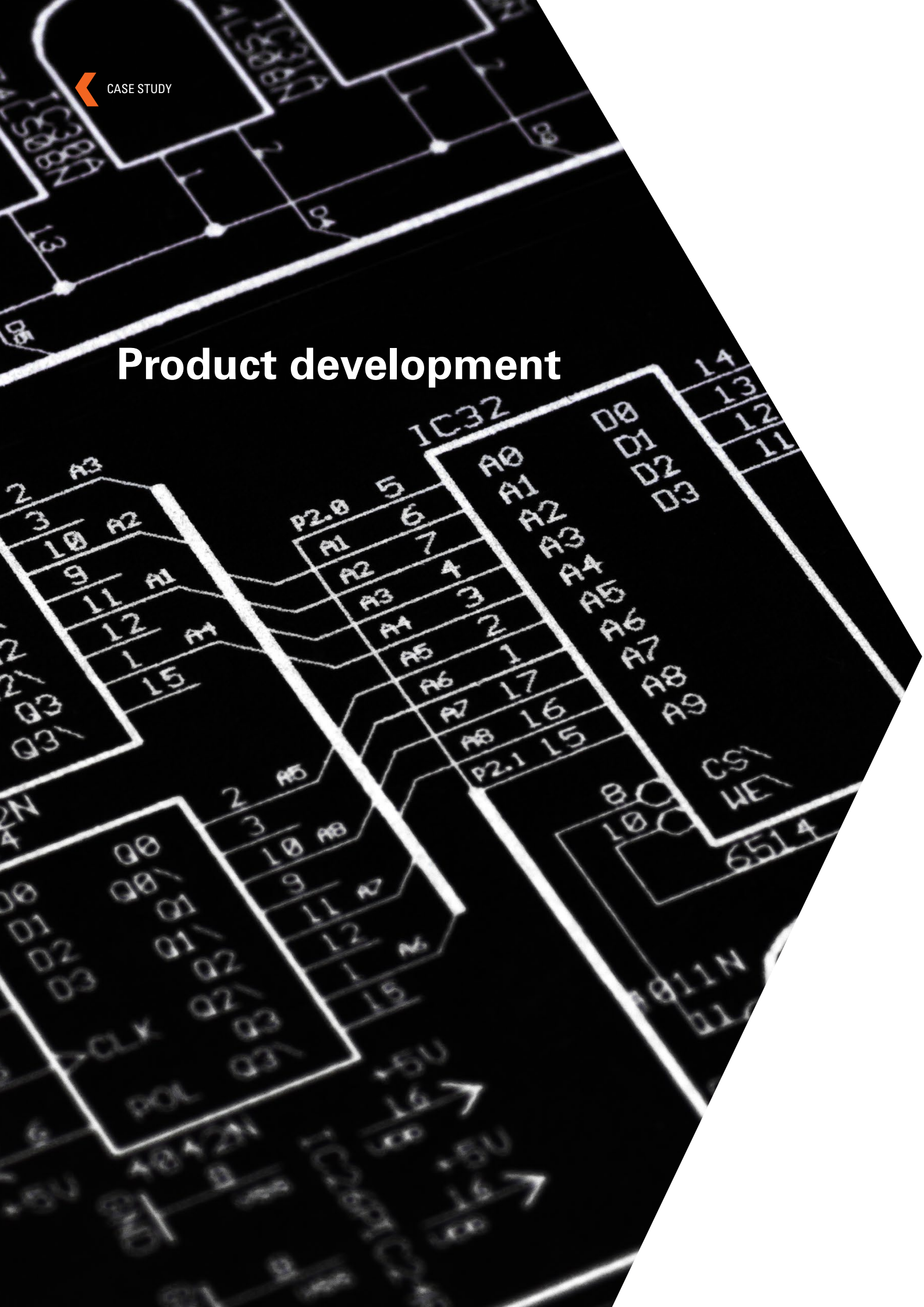
PATENTED TECHNOLOGY



### VeSTIMs® MRS

8 weeks use of a VeSTIMs® mattress lead to a +336% increase in resting blood flow, 0.52kg increase in muscle (Fat Free) mass, +197% increase Endothelial function and skin temperature at the big toe warmed from an icy cold 22.9°C to a cosy 26.4°C. Participants also reported feeling better and free for morning stiffness.

# Product development



**The programme began with a small-scale study in which the brothers met with both clinicians and elderly patients, as well as consulting with Dr Rodney Gush, Lead Applications Scientist at Moor Instruments, the global leader in developing products for tissue blood flow and oxygen assessment.**

Gary Baker acknowledges that use of the Moor instruments allowed a unique insight into the effects that different pressures have on endothelial function, important as endothelial dysfunction is the precursor to cardiovascular disease.

The primary measure for preventing and treating cardiovascular disease is to improve endothelial function through physical exercise. However, this becomes progressively more difficult due to the effects of ageing.

Baker realised that it might be possible to supplement or replace exercise by simply sleeping on a specially designed mattress. The resulting product – Vestims – which is subject to multiple patents, uses a series of air tubes that sequentially and slowly apply and relieve pressure against the skin tissue, making it imperceptible in use. This is controlled by a special medical algorithm that optimises the stimulation of endothelial function, improving general circulation without causing discomfort or disturbed sleep.

The theory contradicts the traditional view of many bed manufacturers who traditionally view repositioning during sleep as a negative, often describing it as 'fidgeting' or 'restlessness'. Some manufacturers champion the design of beds and mattresses with

claims of weightlessness and zero pressure, with the intention of keeping users motionless for long periods of time.

The alternative perspective, credited to Keane in 1978, is that humans are a terrestrial species designed to sleep on the ground and that gravity compresses blood vessels between the ground (or mattress) below them and the bone above them. This impairs localised blood flow, resulting in potential skin tissue injury if unrelieved. Discomfort resulting from lack of movement causes partial waking and repositioning approximately once every 11.6 minutes, or 40 times a night. These movements cause significant changes in the interface pressures being applied to different parts of skin tissue, resulting in an immediate improvement in localised blood flow and stimulated endothelial function, leading in turn to long-term health benefits.

It is this alternative view that Baker subscribes to, leading to the creation of a mattress that effectively simulates this natural movement, creating a perpetual, mild exercise throughout the period of natural sleep whilst providing the comfort of a traditional domestic mattress.

## USER RESEARCH STUDY

In 2019, Baker successfully completed a three-year master's degree specialising in the effects that mattresses have on blood flow and health, at Plymouth Marjon University. His accompanying, widely published research paper is entitled 'Vascular endothelial function is improved after active mattress use'. The study is based on ten healthy participants (four male, age  $52.7 \pm 8.5$  years, six female age  $51.8 \pm 17.5$  years) and concluded that active mattress use for eight weeks led to significant improvements in resting blood flow (+336%) and endothelial function (+197%). This is important because everything that humans do is linked to blood flow and endothelial dysfunction is the precursor to cardiovascular disease.

Also of clinical significance is that skin temperature improved by  $3.5^{\circ}\text{C}$  at the toes whilst remaining stable throughout the wider body. This is important because many people suffer from painfully cold feet, even at room temperature, one of the reasons why some homes for elderly people are maintained at such high temperatures.

The participants, who had a mean average weight of only 76kg, experienced a significant increase in muscle or fat free mass following the eight-week study. This is important because elderly people can suffer from a progressive loss of muscle mass which can lead to frailty and balance issues, frequently leading to falls and further health problems. It is believed that use of the Vestims mattress will 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 implications for users of any age and in any state of health due to its ability to simulate exercise during sleep.



## CERTIFICATION TO ISO 13485:2016

Taking the new mattress to market required an accredited quality management system specifically designed for the manufacture of medical devices as part of the UK Medical Device Regulations 2002. However, the COVID-19 pandemic took hold, and the decision was taken to consolidate the business in preparation for a product launch in February 2022.

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## IMPLEMENTING ISO 13485:2016: THE PROCESS

Gary Baker recalls SGS Key Account Manager Lynette Wilson’s support during the initial enquiry stage in reviewing current processes and defining requirements. He estimates that tens of thousands of pounds were saved by restructuring the business prior to proceeding with the application.

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

The internal auditing procedure is a very important part of ISO 13485 because it gives all staff involved with the project the opportunity to review every single 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 in 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 which involved some 40 hours’ preparation.



Owing to a COVID lockdown, the first audit was conducted virtually via Microsoft Teams, with Squirrel Medical's remote staff being able to join the meeting quickly and easily. SGS auditor Ali Borazjani began by accurately detailing the process so that everybody was aware of their respective contributions to the day, including answering questions and providing the requisite documentation.

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The stage one audit revealed several minor non-conformances, which were detailed thoroughly in a written document together with a verbal explanation as to why these were an issue and steps required for their remediation. The final audit stage was conducted in person by SGS's Tony Kermath, who again receives praise from Gary Baker 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, certification to ISO 13485 was awarded in mid-October 2021.

## WHY SGS?

Squirrel Medical's research partner Moor Instruments is certified as meeting the requirements of Directive 93/42/EEC for a number of its medical devices, with SGS as the Notified Body.

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

## HOW CERTIFICATION HAS BENEFITED THE BUSINESS

Gary Baker says: *"ISO 13485 is a quality management system that really works, it's brilliant. I have to admit that initially we were sceptical, but it has been well thought out by experts and has improved our processes and increased our productivity."*

He adds that it is sensible to use the system until it becomes 'habitual and normal' before finalising an audit date.

Squirrel Medical has found the standard to be highly adaptable, tying many aspects of the business together. But Baker claims that working with SGS has meant that it can be leveraged even more effectively.

Because all employees are included in the audit, certification has boosted internal competence and capability, with everyone understanding the entire business and the importance of the role within it, with Baker suggesting that it has brought about a significant culture change.

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 subsequently specified the standard for hospital applications, opening up exciting new direct selling opportunities for Squirrel Medical.

## ADVICE TO ORGANISATIONS CONSIDERING CERTIFICATION TO ISO 13485

Gary Baker 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.

Being confident and relaxed is also important, adds Baker, and in the same vein not inviting too much pressure by rushing the process. SGS recommends between one and two years from start to finish.

Finally, he recommends SGS's two-day internal auditor course as 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 prior to 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."*

### **Squirrel Medical:**

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## WORKING WITH SGS

On working with SGS, Gary Baker says: *“They were very helpful, leading us through the process and explaining how to resolve any issues in the easiest and most effective way. We have pulled together our respective work processes with the result of improving efficiency and productivity.”*

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

He concludes: *“I have no hesitation in recommending SGS to anybody looking to seek ISO 13485 accreditation and have indeed done so.”*

## ABOUT SGS

We are SGS – the world’s leading testing, inspection and certification company. We are recognised as the global benchmark for quality and integrity. Our 96,000 employees operate a network of 2,700 offices and laboratories, working together to enable a better, safer and more interconnected world.

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WHEN YOU NEED TO BE SURE

