



Getting devices to market: efficiency without compromise

A start-up manufacturer, releasing its first device ahead of the biggest regulatory change the industry has seen for over a decade. Despite these challenges, Coala Life experienced a “successful and timely” product launch.

Market access for medical devices brings a number of challenges, from making sure devices and processes are compliant, to making sure commercial goals are met. BSI understands these challenges; our experts are industry and regulatory specialists, and many have experience launching products to market. Find out how we used this expertise to support Coala Life’s first product launch.

What were Coala Life looking for?

Coala Life required efficient product certification in the form of CE marking to secure market access to the European Union (EU). It was also looking for a Notified Body that could provide ISO 13485 Quality Management System (QMS) assessment. There was the added complexity of ensuring compliance of an innovative digital device, using an app and a cloud based service. This required a Notified Body with the relevant technical expertise to conduct a thorough review of technical documentation within its timelines, and auditing capability to assess its processes.

About Coala Life

A Swedish start-up, Coala Life's first product to market is the Coala Heart Monitor: a remote cardiac monitoring device that allows simple monitoring and analysis of the heart. The Coala Heart Monitor consists of hardware, a smartphone app and a cloud based service. The device is designed to be used by individuals at their convenience, allowing data analysis in minutes. It also allows clinicians to remotely monitor users and conduct digital cardiac assessments.

What made Coala Life choose BSI?

According to Philip Siberg, CEO at Coala Life, **“We spoke with all major Notified Bodies on the market to assess and value the ideal partner for us. The choice was to work with BSI.”** Based on recommendations from other BSI clients, BSI's global presence, allowing scalability of its business, and the **“strength and stability of BSI in the international market”**, the choice was easy according to Siberg. The decision was cemented by the BSI Active Devices team having the right expertise to certify a device with both hardware and software aspects, and being able to offer Coala Life a timely technical documentation review service for CE marking.

“BSI’s solutions have enabled the successful and timely launch of the Coala Heart Monitor to the Swedish market.” *Philip Siberg, CEO at Coala Life*

The challenges of compliance

Bringing your company's first product to market in a highly regulated industry is challenging enough; Coala Life had to create a full, compliant QMS and Technical File for the product from nothing. Siberg acknowledges that **"implementing a new QMS and developing a medical device is complex and challenging."** Added to this was the technical challenge of designing an innovative product that had to meet the stringent regulatory requirements. Siberg gives the following example: **"correctly defining the scope and labelling was a challenge for this novel system."**

Dedication to achieving timely market access allowed Coala Life to navigate the regulatory challenges. The team worked collaboratively to support the BSI product review, and benefitted from access to the dedicated Product Expert, who was able to provide expertise within the bounds of the role of the Notified Body. This allowed BSI to work efficiently and support Coala Life with an efficient yet robust conformity assessment.

In addition, the product was launched in 2017, just as both ISO 13485 and the Medical Devices Directive (93/42/EC), which the Coala Heart Monitor has to comply with for European market access, changed. The latest version of the Standard was published in February 2016, and the Directive was replaced by the new Medical Devices Regulation in

May 2017. These revisions bring more robust requirements, affecting multiple aspects of the Technical File, including risk management, clinical evaluation and traceability through the supply chain. Awareness of these changes is important to help Coala Life prepare for and implement the transitions, which will need to be addressed in the current certification cycle. Siberg comments that this **"made the process slightly more difficult, but BSI's guidance and applicable documentation helped us on the way."**

Did Coala Life meet its market access goals?

Siberg thinks so: **"Yes, indeed. We received ISO 13485 certification and the Coala Heart Monitor was CE-approved within our timelines."** As CE marking is a prerequisite for placing the device on the market in the EU, and both CE marking and ISO 13485 certification can support market access in other territories, it was essential that Coala Life secured certification for its device. By working with BSI, taking advantage of our technical expertise and utilizing the focused technical documentation review service, Coala Life was able to meet its commercial goals with the confidence of using a trusted Notified Body. And it has seen the benefits already: **"Feedback from the market is very positive, we already have satisfied customers,"** comments Siberg.

Find out more about BSI's trusted technical documentation review services

BSI has a strong commitment to providing the most experienced and efficient routes to market. This is why we offer you **CE-Excellence**, our technical documentation review services:

CE-Standard

The BSI CE-Standard review service allows you to work closely with your assigned BSI Product Expert on your product certification. These reviews are conducted remotely, with communication between you and your BSI Product Expert, as required.

CE-Dedicated FastTrack*

The CE-Dedicated FastTrack review service allows you to book your technical documentation review in advance. The service is conducted remotely with your BSI Product Expert, who uses the time allocated to your company to conduct a focused review of your technical documentation. This allows you to interact with your BSI expert, providing them information during the review. The CE-Dedicated FastTrack service improves the efficiency of the process, and provides predictability in your planning of the review.

CE-Onsite FastTrack*

The CE-Onsite FastTrack review service is conducted at your premises; a BSI Product Expert visits the facility for a period of time. It allows for dynamic communications and opportunities for immediate responses to questions.

**"We spoke with all major Notified Bodies...
The choice for us was BSI."** *Philip Siberg, CEO at Coala Life*

* Note: BSI CE-Dedicated FastTrack and CE-Onsite FastTrack technical documentation review services do not guarantee a certificate will be issued within a certain number of days, but are based on completing the review process with either a positive or negative recommendation. These services are not available for devices utilizing animal tissue, blood derivatives or medicinal substances.

bsi.

BSI Group : 

The Mira Corporate Suites
A-2, Plot No. 162, Ishwar Nagar
Mathura Road
New Delhi 110065
India

T: +91 11 2692 9000
F: +91 11 2692 9001
E: info.in@bsigroup.com

To find out more about CE-Excellence,
or to speak to us about your product review,
call us now or visit our website

Call: **+91 11 2692 9000**
or visit: **bsigroup.com/ce-excellence**

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