



CASE

## Fast track for fertility test for men

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In connection with the CE approval and the launch of SwimCount, which is the world's first reliable home test of men's sperm quality, Medicologic contributed with their expertise in gathering and writing the documentation required by the British Standards Institution (BSI).

- Having secured the CE approval, we are now ready to sell SwimCount from our website [www.swimcount.com](http://www.swimcount.com), says CEO Jacob Moellenbach, MotilityCount. - We are also well underway in concluding sales agreements with Danish and British customers.

SwimCount solves two problems. It enables men to carry out the test at home - easily, safely and quickly, so any embarrassment about having to go to a fertility clinic does not delay a necessary examination, change of life style, or treatment. And SwimCount measures the sperm cells' ability to swim towards the woman's egg cell, which determines the sperm quality. Existing tests measure only the quantity, which can give a false picture.

## **Outside Help**

In December 2014 Jacob Moellenbach was, like many entrepreneurs, in need of gaining an overview of the procedures involved in applying for CE approval. He recalled having discussed the matter and having received a business card at the Medico Bazar half a year earlier, and he contacted Medicologic.

Here Senior Professional Consultant Frank Petersen took care of the job. He is familiar with approval procedures from both sides of the desk from a long career both with regulatory authorities and in manufacturing. He spent three months gathering the required technical file documentation, which was delivered to BSI at the end of March.

## **Good Communication**

- It is always the company's job to carry out tests and provide documentation, says Frank Petersen. - Sometimes, it can be difficult to understand the rationale behind the documentation requirements when you have worked on developing a product for a long time, but the rules have been created

to protect the consumers. Jacob and the team at MotilityCount understood this and did what was required quickly and precisely. My task was to 'pack' the documentation.

- Frank was fast and good at communicating exactly which documentation we should provide, and how it should be written, says Jacob Moellenbach. - There was no hesitation. I am extremely pleased with the cooperation.

### Fast Track

MotilityCount had already decided to put the approval procedure on the 'fast track' - that is, pay for a faster processing at BSI – so SwimCount could be ready for the market already this summer. BSI has actually reacted quickly, and similarly, Medicologic was immediately ready to answer the questions that were raised by BSI in three rounds, and provide additional documentation.

- It is important to respond promptly, says Frank Petersen. - When we deliver the required documentation, while the task is 'top of mind' at the BSI, they will process it faster.

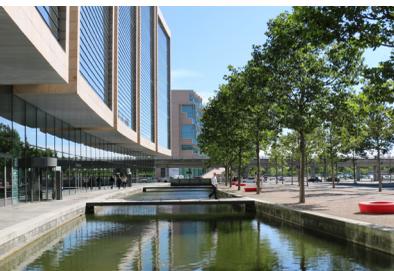
Danish Quality at the British Market  
Irrespective of choice of EU country for the approval application, the CE approval will be valid in the entire European market. Nevertheless, the choice of BSI turned out to be an advantage:

- Although our British distributor is very pleased that the product is Danish, because this associates it with innovation and high quality, he feels more confident with a CE approval from BSI, so SwimCount will be twice as well received in the market, says Sales Director Mogens C. Thomsen, MotilityCount.

### Supplement to Fertility Clinics

The point of using SwimCount is that a home test at a reasonable price will get men to test their sperm quality earlier, so they can take appropriate steps towards treatment for childlessness. This can be done with advice from their own doctor or from specialised fertility clinics. It makes SwimCount a supplement to fertility clinics, since it will encourage more men to seek help earlier.





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### About Medicologic

Medicologic A/S is a consultancy firm that has advised Danish medical device companies for over a decade on the successful development and validation of medical devices to increase patient safety and to ensure the best possible treatment methods. Our Medical Device Consulting shows that we are meeting market needs and the requirements of the medical device field.

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