

## **PRESS RELEASE**

**5<sup>th</sup> July 2019**

### **Danish company receives the US Food and Drug Administration (FDA) 510(k) Clearance for its at-home SwimCount™ Sperm Quality Test**

As per 27<sup>th</sup> June 2019 MotilityCount ApS has received FDA 510(k) Clearance for its SwimCount™ Sperm Quality Test which means that the product can now be legally marketed in the US Market.

The SwimCount™ Sperm Quality Test is an at-home qualitative test that detects sperm concentration above or below 5,000,000 Progressive Motile Sperm Cells per mL (PMSCs/mL) and the test is intended for use as an aid in the determination of a man's fertility status. For *in vitro*, over-the-counter use.

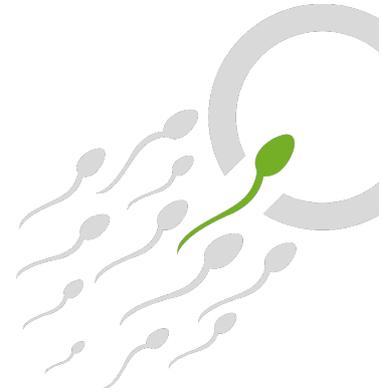
“The FDA Clearance is a huge milestone and achievement for MotilityCount ApS and will thus very soon make it possible for Americans to buy and take a sperm quality test in the privacy of their own home. In this respect MotilityCount ApS has already entered into a Distribution Agreement with an important American company widely recognized for the commercialization of at-home products both to the Online channel as well as to the huge Offline Retail Pharmacies Channel says Mogens C. Thomsen, MotilityCount ApS CEO”.

Generally, the World Health Organization (WHO) states that: “Too many couples with fertility problems wait much too long to have examinations to learn why they do not get pregnant. However, the time factor – and especially the woman’s age – is very important when it comes to infertility treatment. Women’s fertility declines dramatically with age and thus it is important to seek treatment as early as possible. The SwimCount™ Sperm Quality Test provides a fast and reliable result about the man’s sperm quality, and thereby provides a shortcut towards the right treatment instead of a ‘wait and see’ for too long”, Jacob Møllenbach explains, MotilityCount ApS Co-Founder”

The point of differentiation to other at-home sperm tests is that the SwimCount™ Sperm Quality Test makes use of the MotilityCount ApS patented SwimCount™ Membrane Swim-Up Technology and that this test is measuring the number of PMSCs per mL which are the only sperm cells that can reach and fertilize an egg in a natural way.

"SwimCount™ is a revolution for the early diagnosis of male infertility, which we must remember is the cause of 40% of infertility problems. Another 40% is due to women and the remaining 20% to unknown causes," says Dr. Marcos Meseguer, Scientific Supervisor of IVIRMA Valencia and collaborator in the SwimCount™ Sperm Quality Test Clinical Study. "We should not underestimate the importance of the male factor in reproduction and therefore, a test like this, which allows men to obtain an early diagnosis with a high degree of reliability in the comfort of their own home, is a breakthrough," he explains and further stresses that an advanced age is also a factor that influences the male fertility (*IVIRMA Global is the largest Assisted Reproduction Group in the world with 70 clinics in 13 countries*).

“The FDA Clearance gives the company the license to sell in the US market being the world’s biggest market for home-testing and will thus result in a very important increase in turnover of the company, says Mogens C. Thomsen MotilityCount ApS CEO”.



Read more on [www.swimcount.com](http://www.swimcount.com)

Contact:

CEO Mogens C. Thomsen, telephone +45 40 60 33 03- [mct@motilitycount.com](mailto:mct@motilitycount.com)

About MotilityCount ApS:

Danish company MotilityCount ApS developed SwimCount™ Sperm Quality Test. The company was founded in 2010 by entrepreneurs and scientists with many years of experience in IVF treatment.

Behind the company are primarily private Danish investors and Danish Welfare Tech Invest.

About men's sperm quality and infertility:

Declining sperm quality and infertility are fast growing problems world-wide with 70 million cases of infertility of which 40-50% are caused by male factors (*© 2017 American Society of Andrology and European Academy of Andrology*).