

Press Release

## MotilityCount obtains EU MDR Approval for New Innovative Clinical Sperm Purification Method

MotilityCount ApS can now sell the Danish sperm purification method. A European study made by IVIRMA Global shows convincing results.

Valby - Copenhagen, DENMARK, October 8<sup>th</sup>, 2024 - With the launch of a brand new method for sperm purification for Assisted Reproductive Technology (ART), the Danish company MotilityCount ApS has reached a new milestone. The **SwimCount™ Harvester** has been approved under the new European Medical Device Regulation 2017/745 (EU MDR) and is now ready for sale in Europe. The MDR has replaced the Medical Device Directive (MDD) and imposes significantly stricter requirements to ensure patient safety and product standards. Behind the development of the new sperm purification method, aimed at gynecologists and fertility clinics, are Danish specialists in fertility treatment.

"It is no secret that it takes time, money, and patience to meet the EU's stringent MDR requirements. Therefore, it is a huge relief to reach this point. The world is in the midst of a global fertility crisis. Couples struggle for years to achieve pregnancy. Several studies already suggest that our new product can make a difference. That is why it is such a significant milestone that we can now enter the EU market," says Mogens C. Thomsen, CEO of MotilityCount.

### Study Concludes: Groundbreaking Method

The **SwimCount™ Harvester** is a simple and safe method for separating the best sperm cells for fertilization much faster. In a clinical study, where this new sperm purification method was tested against one of the most commonly used methods to date, the SwimCount™ Harvester demonstrated impressive results. The study was led by renowned researcher and fertility embryologist, Ph.D., Marcos Meseguer, from IVIRMA Global, the world's leading fertility group based in Valencia, Spain:

"The SwimCount™ Harvester is a novel sperm selection methodology to be taken into account in the coming years. Preliminarily, the significant improvement in sperm quality stands out. The research showcases the potential of microfluidics to revolutionize the field with its ability to separate sperm based on progressive motility. SwimCount™ Harvester enhances sperm quality parameters more effectively than traditional methods such as Density Gradient Centrifugation (DGC) and Swim-up."

The SwimCount™ Harvester utilizes sperm's natural swimming ability to separate Progressive Motile Sperm Cells (PMSCs) from other sperm. The study vs DGC shows that this new selection method increases the number of PMSCs by 75% while reducing the DNA fragmentation (i.e., damage to the genetic material) by 66%. Additionally, it improves normal sperm morphology by 33%. The process is also easier to perform in the lab, as the number of necessary steps in the selection technique has been significantly reduced. It all takes place in a closed system, which can only be operated in one way, reducing the risk of human error and saving time. The new method also reduces the amount of culture media required. Overall, the method could greatly impact the chances of achieving a successful pregnancy.

### Danish Professor Excited

In Denmark, the Fertility Clinic at Skive Regional Hospital is conducting a quality study of the

SwimCount™ Harvester. Preliminary tests show a trend towards higher sperm concentration when using SwimCount™ Harvester compared to DGC.

Professor Peter Humaidan from the Fertility Clinic at Skive Regional Hospital, who has researched male fertility for many years, says:

"This is not just a purification method. It is an indicator of having 'super sperm.' We know that 20% of Danish men with completely normal sperm concentration have such severe DNA damage that achieving pregnancy at home is almost zero. When we work with the sperm in the lab, their success rates are also significantly lower. So, if we have a purification method like the one, we now have, which biologically and gently allows the best sperm to pass through, we are essentially dealing with 'super sperm.' We fully trust that this new method will yield positive results."

Learn more about **SwimCount™ Harvester** at [www.swimcountharvester.com](http://www.swimcountharvester.com)

Press photos can be downloaded at [www.motilitycount.com](http://www.motilitycount.com)

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**About the Clinical Study**

The clinical study of the **SwimCount™ Harvester** conducted by IVIRMA Global in Valencia, Spain, was part of the European funding program Eurostars. IVIRMA Global has been part of the consortium involved in developing and testing the SwimCount™ Harvester. The partnership is co-financed by the EU through Horizon Europe, a support program for research, development, and innovation.

In addition to the clinical study on SwimCount™ Harvester's performance compared to Density Gradient Centrifugation (DGC) and Swim-up, IVIRMA Global researchers are conducting an embryo quality study using sperm purified with the SwimCount™ Harvester for fertilizing eggs. Results half-way through the study show a 22.8% improvement in the Embryo Quality Assessment compared to the widely accepted method today.

More knowledge about the interim clinical study from IVIRMA Global in Valencia, Spain can be found at [www.swimcountharvester.com](http://www.swimcountharvester.com)

**About MotilityCount**

MotilityCount ApS specializes in developing technologies and products for sperm analysis and microfluidic sperm purification.

In addition to the **SwimCount™ Harvester**, which is developed and produced 100% in Denmark, MotilityCount is behind the renowned **SwimCount™ Sperm Quality Test** for men, which was launched in Europe in 2015. This at-home test allows men to assess their sperm quality within just 30 minutes without first needing to visit a doctor or fertility clinic. The goal has been to help men detect low sperm quality earlier and more easily. The product was launched in the USA in 2019 and is sold under a US FDA 510(k) and a CE IVDR in Europe as well as in other countries.

MotilityCount is also behind the brands **VetCount™ Harvester** and **PetCount™ Sperm Quality Test for Dogs** and is funded by private investors, Danish foundation Welfare Tech Invest and Export and Investment Fund of Denmark (EIFO).