



## EU Declaration of Conformity

Manufacturer: MotilityCount ApS  
Hvidkildevej 48, 2.  
2400 Copenhagen  
Denmark

Manufacturer Identification Code: SwimCount Ref. 1000.1

Notified Body: BSI, NB Number 0086

Certification Number BSI: CE 620348

Product Details: SwimCount self-testing device is semi-quantitative test kit for male infertility. Infertility is determined by measuring the concentration of motile sperm cells as either above or below 5 million motile sperm cells as indicator for male fertility.

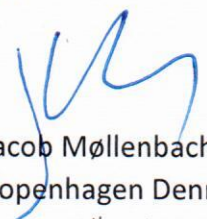
Classification: IVDD, Non Annex II, Self-Testing Device

Conformity Assessment Route: Annex III including §6, EC Declaration of Conformity

We hereby declare that the SwimCount self-test device complies with the requirements of Directive 98/79/EC of the European Parliament and the Council of 27<sup>th</sup> October 1998 on in vitro medical devices.

A Quality System in accordance with EN ISO 13485 and a Risk Management Plan in accordance with 14971 have been established for the device.

Signed



Jacob Møllenbach  
Copenhagen Denmark  
Date: 28<sup>th</sup> July 2015

MotilityCount ApS. Hvidkildevej 48, 2. 2400 Copenhagen, Denmark.