Press release
February 16, 2009
Göteborg, Sweden

Swemed Sense™ approved by the American Food and Drug Administration

Vitrolife has received approval from the American Food and Drug Administration, so-called 510(k) clearance, for its new needle for the collection of human oocytes, Swemed Sense™ (patent pending), which reduces the risk of tissue damage and pain. The needle, which has previously received European approval, a so-called CE mark, and which was launched at ESHRE in 2008, has received a very positive response and publicity. Swemed Sense™ will now be launched in the USA.

Swemed Sense™ combines the good properties of Vitrolife's previous needles with a new way of designing the front part and tip, so that the patient will experience less discomfort and so that the risk of bleeding is reduced. "This is the first product that applies a new technical principle for oocyte collection needles. We believe in this principle very much," says Anette Jäderberg, Marketing Director at Vitrolife.

The Swemed Sense™ oocyte aspiration needle is designed with a thinner front part and tip so as to minimize tissue damage, bleeding and pain. However, the rear part of the needle has a larger diameter. This makes the needle stable and therefore does not reduce the handling ability. Furthermore, the procedure is just as fast as when a thicker needle is used, which is not the case with uniformly thin needles. A patent application has been submitted for Swemed Sense™ in all major markets.

The response after the launch of Swemed Sense™ in Europe has been incredibly positive.

It is estimated that the market for Swemed Sense™, which is used in the collection of oocytes for IVF, amounts to approximately 50 million Euros worldwide.

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Vitrolife is a global biotechnology/medical device Group that works with developing, manufacturing and selling advanced products and systems for the preparation, cultivation and storage of human cells, tissue and organs. The company has business activities within three product areas: Fertility, Transplantation and Stem Cell Cultivation.

The Fertility product area works with nutrient solutions (media), cryopreservation products and advanced consumable instruments such as needles and pipettes, for the treatment of human infertility. The Transplantation product area works with solutions and systems to evaluate and maintain organs outside the body in order to select usable organs and keeping them in optimal condition while waiting for transplantation. The Stem Cell Cultivation product area works with media and instruments to enable the use and handling of stem cells for therapeutic purposes.

Vitrolife today has approximately 150 employees and its products are sold in more than 80 markets. The company is headquartered in Gothenburg, Sweden, and there are subsidiaries in USA, Australia, France and Italy. Production facilities are located in Sweden and the USA.

The Vitrolife share is listed on NASDAQ OMX Stockholm, Small Cap.

This is a translation of the Swedish version of the press release. When in doubt, the Swedish wording prevails.