

2004-06-28

VITROLIFE PRODUCTS RECEIVE EUROPEAN APPROVAL

Vitrolife has received European approval (CE mark) for a complete series of products within ART (Assisted Reproductive Technology). “This gives us competitive strength in established markets and enables us to more easily introduce the products on new markets” says Tony Winslöf, Director of Marketing at Vitrolife.

Vitrolife has received CE approval for the products G-RINSET[™], G-MOPST[™], G-SPERM[™], G-FERT[™], G-1[™] (version 3), G-2[™] (version 3), G-MMT[™], EmbryoGlue[®], G-PGD[™], G-FreezeKit Blast[™] and G-ThawKit Blast[™]. This means that all of Vitrolife’s GIII culture media products (the latest developed IVF media system focusing on mimicking the natural environment for gametes and embryos) are now CE marked which gives the company additional competitive strength in the European countries where the products have already been introduced. Based on available official statistics, the European market is the largest IVF (In Vitro Fertilization) market in the world, representing more than 50% of the 500,000 treatments performed worldwide each year.

“An increasing number of clinics today demand CE marked culture media products. Their quality systems and supplier selection systems rule out products that do not meet the requirements for a CE marking” says Tony Winslöf, Director of Marketing at Vitrolife. “The approval signals to the market that ART culture media products now definitely are being classified as medical devices and have to meet the requirements of the European Medical Device Directive. This also means that we will now be able to present our products to the new members in the European Union, which we know hold a great potential. These markets have previously been more or less closed to us since conflicting local regulations have made it virtually impossible to compile the necessary documentation for application.”

“To my knowledge this is the first complete ART culture media system that receives the CE mark” says Hans Lehmann, Vitrolife’s Manager of Development. “It is positive for Vitrolife in many aspects, the most apparent one being the fact that regulatory authorities acknowledge our products as being safe and efficacious in their intended use.”

The Quality Control Director of Vitrolife, Göran Mellbin, emphasizes that the CE mark is yet another recognition of the high quality standard which is essential for all Vitrolife products.

Gothenburg, June 28, 2004.

Vitrolife AB (publ)

For further information, please contact;

CEO:
Dr. Magnus Nilsson
Tel: +46 31 721 80 00
Mobile +46 708 22 80 61
mnilsson@vitrolife.com

Acting Marketing Director:
Tony Winslöf
Tel: +46 31 721 80 00
Mobile +46 708 22 80 15
twinslof@vitrolife.com

Vitrolife is a global biomedical corporation that works with products for cell and tissue technology. The Vitrolife group consists of the parent company, Vitrolife AB (Publ) and two wholly owned subsidiaries: Vitrolife Sweden AB (Gothenburg, Sweden), Vitrolife Inc. (Denver, Colorado). The group’s operations is focused on three geographic areas.

- Europe/Middle East
- The Americas
- Rest of the World

Vitrolife’s business concept is to develop, produce and sell advanced products and systems for the preparation, cultivation, preservation and support of cells, tissues and organs.