



FUJIFILM Irvine Scientific Receives CE Mark Approval for Multiple ART Media
Innovative ART products now available in Europe

SANTA ANA, California, 08 October, 2019: FUJIFILM Irvine Scientific, Inc., a world leader in the innovation, development and manufacture of cell culture media and Assisted Reproductive Technologies (ART), today announced the receipt of CE Mark approval for key ART products. CE Marking is a distinction that the products conform to standards set by the European Union health and safety legislation.

The products that received CE Marking include:

- **Continuous Single Culture-NX (CSCM-NX) and Continuous Single Culture-NX Complete (CSCM-NXC).** A clinically-proven, low lactate single-step medium that helps improve blastocyst development. Available with and without human serum albumin (HSA) protein supplement.
- **Arctic Sperm Cryopreservation Medium.** A TEST-yolk buffer-free, dual-buffered medium designed for modern sperm processing.
- **Multipurpose Handling Medium (MHM) in a 12X12 configuration.** A dual-buffer handling medium that maintains a stable environment for all manipulations performed outside of the incubator, such as oocyte retrieval and rinsing, sperm processing and intracytoplasmic sperm injection, (ICSI), and embryo transfer.

FUJIFILM Irvine Scientific is devoted to meeting or exceeding regulatory standards worldwide and was one of the first ART manufacturing companies in the United States to receive ISO 13485 Quality System certification, the rigorous international quality assurance standard designed specifically for medical devices. Each product is manufactured in accordance with the Guidelines for Manufacture of Medical Device and *In Vitro* Diagnostic Products and the Good Manufacturing Practices (GMPs) for Medical Devices.

“FUJIFILM Irvine Scientific leads the way in production of high-quality ART solutions that consistently meet worldwide regulatory requirements,” said Marc Brignola, Senior Director Sales and Marketing, Assisted Reproductive Technologies. “We are pleased to now offer these innovative solutions to all of our European customers.”

Learn about these and other products in the portfolio from our website at www.irvinesci.com/assisted-reproductive-technology.

ENDS

Photo:



For a high-res image contact lorna.cuddon@zymecommunications.com

Notes to Editors

About FUJIFILM

FUJIFILM Irvine Scientific www.irvinesci.com

FUJIFILM Irvine Scientific, Inc., is a worldwide leader in the innovation and manufacture of cell culture media, reagents, and medical devices for researchers and clinicians. The company provides unrivaled service and quality to scientists working in biopharmaceuticals, cell therapy and regenerative medicine, assisted reproductive technology and cytogenetics, and industrial cell culture for the large-scale production of biotherapeutics and vaccines. FUJIFILM Irvine Scientific adheres to both ISO and FDA regulations and operates dual cGMP manufacturing facilities in California, USA, and Tokyo, Japan. The company's consultative philosophy combined with expertise in cell culture and compliance provides customers with unique capabilities and support. For over 45 years, FUJIFILM Irvine Scientific has remained uniquely flexible and focused on media while becoming a strategic global leader in media products and services. FUJIFILM Irvine Scientific, Inc. is a subsidiary of FUJIFILM Holdings America Corporation reporting to FUJIFILM Holdings Corporation.

FUJIFILM Holdings Corporation www.fujifilmholdings.com

FUJIFILM Holdings Corporation, Tokyo, Japan, brings cutting edge solutions to a broad range of global industries by leveraging its depth of knowledge and fundamental technologies developed in its relentless pursuit of innovation. Its proprietary core technologies contribute to the various fields including healthcare, graphic systems, highly functional materials, optical devices, digital imaging and document products. These products and services are based on its extensive portfolio of chemical, mechanical, optical, electronic and imaging technologies. For the year ended March 31, 2019, the company had global revenues of \$22 billion, at an exchange rate of 111 yen to the dollar. Fujifilm is committed to responsible environmental stewardship and good corporate citizenship. For more information, please visit: www.fujifilmholdings.com.

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