

# UTAH MEDICAL PRODUCTS, INC.



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## PRESS RELEASE

### Utah Medical Products, Inc. Receives CFGs from FDA

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Salt Lake City, Utah - On November 16, 2005, Utah Medical Products, Inc. (Nasdaq: UTMD) received confirmation that the U.S. Food & Drug Administration (FDA) is finally honoring UTMD's request to issue Certificate to Foreign Governments (CFGs or "export certificates") that provide nonbinding assurance to foreign entities that UTMD is manufacturing its products in Utah in accordance with the provisions of the Quality System Regulation (QSR). The certification reads,

"It is certified that the above [all of UTMD's] products may be marketed in, and legally exported from, the United States of America at this time. On October 21, 2005, the United States District Court for the District of Utah ruled that the manufacturing plant in which the products are produced is in compliance with current good manufacturing practice requirements for the products listed above."

Although UTMD has never been restricted from distributing its medical devices, either within the U.S. or outside the U.S., for the last two and half years the FDA had refused to provide export certificates. UTMD's inability to timely provide CFGs limited its participation in certain foreign tender offers, and reduced interest by some of its foreign distributors in distributing UTMD's products.

According to CEO Kevin Cornwell,

"Refusing to issue CFGs was the basis for the lawsuit that UTMD filed in June 2003 against the FDA, which until now had gone unresolved. Issuance of CFGs was directed by Congress in order to encourage exports of U.S. manufacturers to foreign countries, improving domestic commerce and providing jobs for U.S. citizens. I believe that the FDA has convoluted the intent of Congress by using the denial of CFGs as a punishment for companies allegedly not following FDA's interpretation of the QSR, which in our case has been proven to be incorrect. We would have preferred that they simply talk to us about their concerns, especially since there was never an allegation of unsafe, ineffective or defective products.

Thankfully, UTMD was able to maintain its ISO certifications and CE Mark on its exported products continuously during the four-year dispute with the FDA. We hope, now that the court case has removed any legal justification for not talking, that the FDA will be open to constructive dialog to clear all past disagreements and establish a sound basis for future interaction."

Utah Medical Products, Inc., with particular interest in health care for women and their babies, develops, manufactures, assembles and markets a broad range of well-established disposable and reusable specialty medical devices designed for better health outcomes for patients and their care-providers. For more information about Utah Medical Products, Inc., visit UTMD's website at [www.utahmed.com](http://www.utahmed.com).