



## OraSure Receives ISO Certification and CE Mark

January 17, 2001

BETHLEHEM, Pa.--(BUSINESS WIRE)--Jan. 17, 2001--OraSure Technologies, Inc. (Nasdaq NM:OSUR) today announced that its Bethlehem facility has received formal certification to ISO 9001, EN 46001 and ISO 13485 standards from TUV Rheinland of North America, Inc.

TUV also granted approval for the Medical Device Directive 93/42/EEC, thereby authorizing CE Mark for the Histofreezer(R) product line.

ISO is the recognized name for an international quality agency working to promote the development of standards for testing procedures to encourage the worldwide trade of quality products and services. ISO 9001 certification indicates that the Company's quality system has complied with all standards encompassing the initial design and development through the production and distribution. ISO certification is a pre-requisite to obtaining a CE Mark, which is required for distribution of medical devices in the European Union (EU) markets.

"We have dedicated significant resources to our Quality System and are pleased with the progress we have made," said Robert D. Thompson, chief executive officer of OraSure Technologies. "Receiving this certification is evidence of the Company's continued commitment to achieving a sound Quality System."

### About OraSure

OraSure Technologies, Inc. develops, manufactures and markets medical devices and diagnostic products for use by public- and private-sector clients, clinical laboratories, physicians' offices and workplace testing. OraSure Technologies is the leading supplier of oral fluid collection devices and assays to the life insurance industry and public health markets for the detection of antibodies to HIV. In addition, the company supplies oral fluid testing solutions for drugs-of-abuse testing. For more information on the company please go to [www.orasure.com](http://www.orasure.com).

This press release contains certain forward-looking statements, including with respect to products and manufacturing and quality procedures. Actual results could be significantly different. Factors that could affect results include loss of key personnel; failure to comply with regulations of the FDA or other regulatory agencies; failure to comply with ISO Certification requirements; obstacles to international marketing of products; loss or impairment of sources of capital; ability to develop product distribution channels; ability to develop new products; development of competing products; market acceptance of oral fluid testing products; and changes in international, federal or state laws or regulations. These factors are discussed more fully in the Securities and Exchange Commission (SEC) filings of OraSure Technologies, including the Registration Statement on Form S-4 filed with the SEC on August 31, 2000 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, and in the Epitec, Inc. Annual Report on Form 10-K for 1999. Although forward-looking statements help to provide complete information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release, and OraSure Technologies undertakes no duty to update those statements.

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