



## MEMSCAP Gets High Quality Medical Certification

*Life devices embedding MEMSCAP technology comply with ISO 13485:2003*

**Grenoble, France and Skoppum, Norway, March 3, 2005** – MEMSCAP (Euronext: MEN), the leading provider of innovative solutions based on MEMS (micro-electro-mechanical systems) technology, today announces it has received the ISO 13485: 2003 Certification for its medical products and devices.

ISO 13485:2003 is a Quality Management System for medical devices. It complements ISO 9001, with which MEMSCAP already complies, and is one of the new harmonized set of certifications for medical devices set by the European Community. Those two qualifications are crucial when it comes to exporting products worldwide, and this is why, with an international client base, obtaining the certification was important for MEMSCAP.

The focus on global standards is today stipulated by certain countries, and the fulfilment of EU Directives (e.g., Active Implantable Medical Devices Directive, Medical Devices Directive and In Vitro Diagnostic Directive) therefore allows the free trade of medical devices, especially since the United States also have based their revised Quality System Regulation (21 CFR 820, Oct. 7, 1996) on the European ISO 9001 and ISO 13485 quality system standards.

Certification of MEMSCAP was obtained after long and thorough audits were conducted in the Company facilities. It is based on the verification of many parameters throughout the production and management chain. The compliance of the quality management system implies traditional requirements for quality management such as design, development, manufacturing, installation and maintenance of medical device but also more specific ones for example design controls, process controls (including environmental controls), special processes, traceability, record retention, and regulatory actions, which are more critical for the medical device industry. This certification is valid for 3 years.

“MEMSCAP market share in the medical and biomedical industry is growing steadily as we are entering new segments as well as providing new products. What we are offering today is a unique mix in the industry because it combines cost effective price and highest quality. At MEMSCAP we are adamant about enhancing the quality of our products where human lives are at stake while decreasing the cost to enable more access to life saving technology” explains Jan Hallenstvedt, newly appointed General Manager of MEMSCAP Standard Products Business Unit

The ISO 9001; 13485 standard is also worked out for the purpose of fulfilling essential requirements in the EU directive for medical equipment (EC directive 93/42) and now governs all processes linked with MEMSCAP medical products (including domes, line sets, blood pressure transducers and sensing elements).

### About MEMSCAP

MEMSCAP is the leading provider of innovative micro-electro-mechanical systems (MEMS)-based solutions. MEMSCAP solutions include components, component designs (IP), design software, manufacturing and related services. MEMSCAP customers include Fortune 500 businesses, major research institutes and universities. The company's shares are traded on Euronext (FR0004155455-MEN), where MEMSCAP belongs to the Next Economy segment. More information on the company's products and services can be obtained at <http://www.memscap.com>

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