



P R E S S R E L A S E

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LNE/G-MED signs recognition agreement with JQA to help medical device manufacturers enter the Japanese market

France's Laboratoire National de Métrologie et d'Essais (**LNE/G-MED**) and the Japan Quality Assurance organization (**JQA**) signed a first recognition agreement on 14 November 2008.

Under this agreement, and in the context of the Japanese regulatory procedure, LNE/G-MED may now work together with JQA on initial audits of quality management systems for manufacturers wishing to market their electromedical and in vitro diagnostic devices in Japan.

Control and renewal audits will be performed independently by qualified LNE/G-MED auditors and recognized by JQA.

For LNE/G-MED customers there are two key advantages. Initial audit time will be shortened, since ISO 13485:2003 certificates already issued by G-MED will be taken into account. And they will enjoy a one-stop service for all their required certification, whether obligatory (CE marking, Japanese regulations) or voluntary (ISO 13485).

A first Japanese certificate will be issued for an LNE/G-MED customer in the first half of 2009.

Under a second recognition agreement to be finalized by June 2009, LNE/G-MED will be authorized to perform audits in Japan for CE marking.

The Laboratoire National de Métrologie et d'Essais (LNE) is a state-owned enterprise with 770 staff. It provides expert services to all companies and bodies concerned with product quality and safety. LNE's five core activities are research, calibration and consulting in metrology, testing and analysis, certification, and training.

CONTACTS

LNE/G-MED certification: Franck Martin – 33 (0)1 40 43 38 55 – franck.martin@lne.fr

Press contact: Vanessa Herrou – 33 (0)1 40 43 40 51 – vanessa.herrou@lne.fr

More information:

www.lne.fr

www.gmed.fr

Laboratoire national de métrologie et d'essais

LNE/G-MED • Notified body n° 0459

Headquarters: 1, rue Gaston Boissier - 75724 Paris Cedex 15 - France • Tel.: +33 1 40 43 37 00 • Fax: +33 1 40 43 37 37 • www.lne.fr • www.gmed.fr