LNE
Le progrès, une passion à partager

Certification
Médical-Santé

Cover Letter LNE - 22083 rev. 4
Issued in Paris on October 9th, 2015

COVER LETTER

Re.: Taiwan Technical Cooperation Programme on Exchange of Medical Device GMP and ISO 13485 Audit Reports

Within the frame of the Technical Cooperation Programme on Exchange of Medical Device GMP and ISO 13485 Audit Reports between R.O.C. DOH Designated Medical Device GMP Auditing Organizations and EU AIMD/MDD/IVD Notified Bodies Partners,

we hereby certify to have delivered conformity certificate to:

MANATEC
21 rue du Stade - Petit Ebersviller
57730 FOLSCHVILLER FRANCE

Location(s):

MANATEC 44 rue de Laborde 75008 PARIS FRA
MANATEC 10 bis rue Jacob Courant 78300 POISSY FRA

Device(s): **Design, manufacture, sales and servicing of Non-Invasive medical devices for hemodynamic measurement by transthoracic impedance signal analysis.**

Certificate n°: **LNE - 7759 rev. 6 with addendum - Effective date : October 3rd, 2014 - Expiry date : October 2nd, 2017.**
Audit report n°: **P110793 -S1 dated August 24th, 2015**

corresponding to the most recent audit of the quality system according to ISO 13485:2003.

The present cover letter, the QS certificate, the complete audit report and the certificate for Foreign Government need to be sent to Taïwan Department of Health for licensing.

Laboratoire national de métrologie et d'essais LNE

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

Renouvelle le certificat 22083-3

GMED_Cover_letter_Taiwan-V4-01-2013

Le progrès, une passion à partager

Certification
Médical-Santé

Addendum of the cover letter n° 22083 rev. 4 **Page 1/1**

This certificate covers the following activities and sites:

- **44 rue De Laborde - 75008 PARIS – France**
  Commercialisation / *Sales*
- **10 bis rue Jacob Courant - 78300 POISSY – France**
  Conception, fabrication, commercialisation, service /*Design, manufacture, sales, service*

****

2 locations

Laboratoire national de métrologie et d'essais • LNE

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr