

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 - 11825 rev. 4 with addendum - Effective date : October 3rd, 2017 - Expiry date : December 31st, 2018**

Audit report n°: **P159917 - R dated from 18th to 19th, July 2017**

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 Taiwan Department of Health for licensing.



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

Renouvelle le certificat 22083-5

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 *IDesign, manufacture, sales, service*

2 locations



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

720 DM 0701- 34 rev 2 du 28/07/2015

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