

## 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 - 21 rue du Stade - Petit Ebersviller - 57730 FOLSCHVILLER - 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°: **GMED - 11825 rev. 5 - Effective date : September 25th, 2018 - Expiry date : December 31st, 2018**

Audit report n°: **P159917 dated July 20th, 2018**

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 President  
Béatrice LYS  
Technical Director**

Renouvelle le certificat 22083-6

**GMED** • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459  
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