

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 - 7759 rev. 11 - Effective date : November 10th, 2020 - Expiry date : October 02nd, 2023**

Audit report n°: **P601476_P2 dated August 30-31, 2021**

corresponding to the most recent audit of the quality system according to ISO 13485 : 2016

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.



DocuSigned by:

Lionel DREUX

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Lionel DREUX
Certification Director

Renouvelle le certificat 22083-10