

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

SEFAM

**144 avenue Charles De Gaulle
92200 NEUILLY SUR SEINE FRANCE**

pour les activités
for the activities

Conception, fabrication, contrôle final, commercialisation, distribution et service après-vente de dispositifs de ventilation de pression positive pour le traitement des troubles respiratoires du sommeil, humidificateurs, logiciels et accessoires associés (voir addendum).

Design, manufacturing, final inspection, commercialization, distribution and servicing of positive airways pressure devices for sleep disordered breathing treatment, humidifiers, software and associated accessories (see addendum).

réalisées sur le(s) site(s) de
performed on the location(s) of

**SEFAM
144 avenue Charles de Gaulle, 92200 NEUILLY SUR SEINE, FRA
SEFAM
10 allée Pelletier-Doisy, 54600 VILLERS-LES-NANCY, FRA**

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485 : 2016 - NF EN ISO 13485 : 2016

Début de validité / Effective date : September 11th, 2018 (included)

Valable jusqu'au / Expiry date : March 15th, 2021 (included)

Etabli le / Issued on : September 11th, 2018



GMED_SQ-F-V0-07-2018

Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 23443-6

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Modifie le certificat 23443-5



**On behalf of the President
Béatrice LYS
Technical Director**

Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites :

SEFAM - 10 allée Pelletier-Doisy - 54600 VILLERS-LES-NANCY :

Version française :

Conception, fabrication, contrôle final, commercialisation, distribution et service après-vente de dispositifs de ventilation de pression positive pour le traitement des troubles respiratoires du sommeil, humidificateurs, logiciels et accessoires associés.

Version anglaise :

Design, manufacturing , final inspection, commercialization, distribution and servicing of positive airways pressure devices for sleep disordered breathing treatment, humidifiers, software and associated accessories.

SEFAM - 144 avenue Charles de Gaulle - 92200 NEUILLY SUR SEINE :

Siège social/Head office

2 sites / 2 sites

GMED	0459
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**On behalf of the President
Béatrice LYS
Technical Director**

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:

SEFAM

144 avenue Charles De Gaulle

92200 NEUILLY SUR SEINE FRANCE

Location(s):

SEFAM 144 avenue Charles de Gaulle 92200 NEUILLY SUR SEINE FRA
SEFAM 10 allée Pelletier-Doisy 54600 VILLERS-LES-NANCY FRA

Device(s): **Design, manufacturing , final inspection, commercialization, distribution and servicing of positive airways pressure devices for sleep disordered breathing treatment, humidifiers, software and associated accessories.**

Certificate n°: **GMED - N° 23443 rev. 6 - Effective date : September 11th, 2018 - Expiry date : March 15th, 2021**

Audit report n°: **P159819-1 dated 30/01/2018 to 02/02/2018**

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.



On behalf of the President
Béatrice LYS
Technical Director

Modifie le certificat 23448-8

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