GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 28577 rev. 5**
Délivrée à Paris le 11 février 2019
Issued in Paris on February 11th, 2019

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

TECHNOLOGIE MEDICALE
101 rue Vaillant Couturier
93130 NOISY-LE-SEC FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

Détendeurs et produits pour l'oxygénothérapie et l'aspiration

Pressure regulators and products for oxygen therapy and suction

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P181091-1, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P181091-1, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **February 11th, 2019 (included)**
Valable jusqu'au / *Expiry date :* **March 11th, 2022 (included)**

GMED SAS GMED SAS

On behalf of the President
Béatrice LYS
Technical Director

GMED_tx2p3-F-V0-07-2018

GMED - 28577 rev. 5
Renouvelle le certificat 28577-4

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Addendum au certificat n° 28577 rev. 5 **page 1/1**
Addendum of the certificate n° 28577 rev. 5
Dossier / *File* N° P181091-1

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Détendeurs et produits pour l'oxygénothérapie et l'aspiration *Pressure regulators and products for oxygen therapy and suction*	**Switch et Flow-Switch** / *Switch and Flow-switch* **Rampe et Dédoubleur de prise** / *Ambulance panel and Y connector* **Flexible** / *Hosepipes* **Robinet direct** / *Direct valve* **RTM3** / *RTM3* **RVTM3** / *RVTM3* **Soupape de Jeanneret** / *Water manometer* **Vanne de vide** / *Direct vacuum valve* **Vanne de vide Australie** / *Direct vacuum valve (Australia)* **Venturi TM2** / *Venturi TM2* **Debflo et Debplus** / *Debflo and Debplus* **Debson TM2** / *Debson TM2* **Humidificateur** / *Humidifier*	**IIa**
	DetregTM / *DetregTM* **Minireg** / *Minireg* **RegflowTM** / *RegflowTM* **RegsonTM2** / *RegsonTM2*	**IIb**

Identification du site couvert et des activités
Identification of location and activities

TECHNOLOGIE MEDICALE – 101 rue Vaillant Couturier – 93130 NOISY-LE-SEC – FRANCE
Conception, fabrication et contrôle final
Design, manufacture and final control

GMED 0459

On behalf of the President
Béatrice LYS
Technical Director

LIETUVOS NACIONALINIS AKREDITACIJOS BIURAS

VS SERTIFIKAVIMAS ISO/IEC 17021

Nr. LA.04.002

SERTIKA

CERTIFICATE

Certificate registration No. 18K.1520 6th of November, 2018

The quality management system is designed, implemented and maintained in the

UAB Medical Technologies LBI

Savanoriu av. 271, LT-50131 Kaunas, LITHUANIA

meets the requirements of the standard
ISO 9001:2015
(LST EN ISO 9001:2015)

Scope of certification:

Design, manufacturing and installation of hospital medical supply systems.

This certificate is valid up to 05th of November, 2021.

Director UAB Ingrida Kusiene

LIETUVOS RESPUBLIKA UAB SERTIKA REPUBLIC OF LITHUANIA

"Sertika" Ltd.
Savanoriu av. 271-255,
LT-50131 Kaunas, Lithuania

sertika@sertika.lt
www.sertika.lt

SERTIKA

CERTIFICATE

Certificate registration No. 18M.1521 6th of November, 2018

Medical devices. The quality management system is designed, implemented and maintained in the

UAB Medical Technologies LBI

Savanoriu av. 271, LT-50131 Kaunas, LITHUANIA

meets the requirements of the standard
ISO 13485:2016
(LST EN ISO 13485:2016)

Scope of certification:

Design, manufacturing and installation of hospital medical supply systems.

This certificate is valid up to 05th November, 2021.
Medical devices. The quality management system is certified since 17th of January, 2013.

Director Ingrida Kusiene

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