G-MED North America, Inc.
Development and Certification Department - Medical Division
10605 Concord Street, Suite 205
Kensington, MD 20895 - USA
Main (301) 495-0477 • Fax (301) 933-1132 • Email: gmedna@lne-gmed.com

Circadiance LLC
1060 Corporate Lane
Export, PA 15632
USA

To the attention of Alex Friedman

Kensington, June 9th 2010

Re: Certification of company quality system
REF.: MHW-1006-07

Dear Alex,

We are writing to inform you of the results of your application for certification further to the audit carried out on 26th - 27th April 2010.

Taking account of:

- The examination of the conclusions of the initial audit,
- The examination of the corrective actions taken following the findings of the audit,
- The opinion of the Comité de Lecture,

The decision is as follows:

CE marking and ISO certification:

Certification according to ISO 13485:2003 CMDCAS and Annex II.3

We are pleased to send you the corresponding CE mark certificate No.18982 rev (0) and ISO certificate No.18981 rev (0), and wish to remind you that this enables you to use the G-MED logo according to the rules of use of the G-MED mark.

We remind you that a copy of this certificate shall be sent to Health Canada with the form f202 (available on http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/f202_rev0-eng.php) within 30 days after its effective date.

Yours sincerely,

Marc-Henri Winter
Certification Project Manager

Encs.: 2 certificates

LNE
Le progrès, une passion à partager

Certification Médical-Santé G MED

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 18981 rev.0

Le LNE certifie que le système de management de la qualité développé par

LNE certifies that the quality management system developed by

CIRCADIANCE, INC.
1060 Corporate Lane,
EXPORT, PA 15632 USA

pour les activités
for the activities

Conception et fabrication de masques pour traitement CPAP ou BiPAP

Design and manufacture of masks for CPAP and BiPAP therapy

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

1060 Corporate Lane Export, PA 15632 USA

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

ISO 13485:2003

Début de validité */ Effective date* **June 9th, 2010 (included)**
Valable jusqu'au */ Expiry date :* **June 8th, 2013 (included)**
Etabli le */ Issued on :* **June 9th, 2010**

For the General Director
Laurence DAGALLIER
Deputy Director

cofrac
CERTIFICATION D'ENTREPRISES & DE PERSONNELS
N° 4-0038
Portée disponible sur www.cofrac.fr

V0 04-07-2007

LNE N° 18981–0
LNE: CMDCAS recognized registrar / This certificate is issued according to the rules of G-MED certification and CMDCAS program requirements / CMDCAS SQ

LNE
Le progrès, une passion à partager

Certification
Médical-Santé

ATTESTATION/ *CERTIFICATE* N° 18982 rev.0
Délivrée à Paris le 09 juin 2010
Issued in Paris on June 9th, 2010

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'Assurance Qualité */ Approval of full Quality Assurance System*
ANNEXE II point 3 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II section 3 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant (nom et adresse) */ Manufacturer (name and address)*

CIRCADIANCE, INC.
1060 Corporate Lane,
EXPORT, PA 15632 USA

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

Masques pour traitement CPAP ou BiPAP

Masks for CPAP or BiPAP therapy

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé L011306-I, 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 point 3 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced L011306-I, the quality system - for design, manufacturing, and final inspection - of medical devices listed here aboved complies with the requirements of the Directive 93/42/EEC, annex II section 3

Début de validité */ Effective date :* **June 9th, 2010 (included)**
Valable jusqu'au */ Expiry date :* **June 8th, 2013 (included)**

For the General Director
Laurence DAGALLIER
Deputy Director

LNE/G-MED	CE	0459

LNE - 18982 rev. 0

VD 04-07-2007