DET NORSKE VERITAS

FULL PRODUCT QUALITY MANAGEMENT CERTIFICATE - EC

Certificate No. 52177-2009-CE-RGC-NA Rev. 1.0
This Certificate consists of 3 pages

This is to certify that the Quality Management System of

Comdek Industrial Corp.

Taipei, Taiwan

for production and final product inspection/testing of

Pulse Oximeter / Patient Monitor

has been assessed with respect to
the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 11 May 2009

NORWEGIAN ACCREDITATION
PROD 002

This Certificate is valid until:
16 February 2014

For DET NORSKE VERITAS CERTIFICATION AS
Norway

Marianne Spæren
Certification Manager

CE

Notified Body No.:
0434

Aud Løken Eiklid
Technical Reviewer

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
	Original certificate	2004-02-16
1.0	**Recertification**	**2009-02-16**

Products covered by this Certificate

Product Description	Product Name	Class
Pulse Oximeter	▪ Portable Pulse Oximeter MD-600P/610P/MD-620P/MD-630P/MD-650P/ MD-660P/MD-670P/MD-680P ▪ Oxi-Capnography MD-660P ▪ Desktop Pulse Oximeter MD-700/MD-710/MD-720/MD-730/MD-750/MD-760/ MD-770/MD-780	IIb
Patient Monitor	▪ MD-800/MD-810/MD-820/MD-830/MD-850/MD-860/ MD-870/MD-880	IIb
Accessory	▪ Sensor: D001/D001-A/D002/D003/R002/R003/R004/R004-i/ R005/RA001/R008/E009 ▪ Probe: HD-T2252-AG/HD-T2252-AS	IIb

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Head office: 9F-1, No. 3, Yuan Qu Street, Nan-Kang, Taipei 11503, Taiwan, R.O.C.

Manufacturer: 7F, No. 1, Alley 6, Lane 235, Pao Chiao Rd., Hsin Tien, Taipei, Taiwan R.O.C.

EU Representative

Comdek Computer System, Schwendistrasse 32, CH-8486 Rikon, Switzerland

Documents reviewed

Document No	Document Name	Version No/Date
2009-IA	TCF	01/20090302

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE