IRISH MEDICINES BOARD
ADVISORY NOTICE

ADVISORY NOTICE

Pulse Oximeter: CMS50DL, CMS50D, CMS60D, CMS60C, CMS50QA, CMS50QB, CMS50F
Patient monitor: PM50, PM60A, CMS6000
Ambulatory Blood Pressure Monitor: ABPM50
Spirometer: SP10
Pocket fetal doppler: Sonoline B, Babysound A, Babysound B.
B-Ultrasound Diagnostic System: CMS600B-3
ECG: ECG300G

IMB Advisory Notice: SN2011(13)
Circulation Date: 13 June 2011

MANUFACTURER / EUROPEAN AUTHORIZED REPRESENTATIVE:
Manufacturer: Contec Medical Systems Co., Ltd.
European Authorized Representative: Shanghai International Trading Corp., GmbH

TARGET GROUPS
Hospital Managers / CEOs
Risk Managers
Clinical Directors
Clinical Engineers
Theatre and Nursing Staff
Purchasing Managers
Nursing Managers
Emergency Departments
Hospital personnel
Medical device distributors

ISSUE
Non-compliant medical devices manufactured by Contec Medical Systems have been supplied to customers in Ireland. These devices do not bear the CE mark as required by the medical device legislation.

BACKGROUND
On the 9th June 2011 the IMB circulated an advisory notice regarding the patient monitors CMS7000 manufactured by Contec Medical Systems SN2011(11). Contec Medical Systems have informed the Irish Medicines Board (IMB) of additional non-compliant Contec Medical system products that may have been supplied to customers in Ireland. These devices do not bear the CE mark as required by the medical device legislation.

SAFETY NOTICE

The affected devices include:
Pulse oximeter: CMS50DL, CMS50D, CMS60D, CMS60C, CMS50QA, CMS50QB, CMS50F.

Patient monitor: PM50, PM60A, CMS6000.

Ambulatory Blood Pressure Monitor: ABPM50.

Spirometer: SP10.

Pocket fetal doppler: Sonoline B, Babysound A, Babysound B.

B-Ultrasound Diagnostic System: CMS600B-3.

ECG: ECG300G.

The manufacturer assured the IMB that all of these devices were manufactured in compliance with the Medical Device Directive 93/42/EEC for CE marking but were supplied to the market without the required labelling.

The manufacturer will circulate a communication to their customers to advise them of the issue and recommended actions.

To date, there have been no incidents reported to the IMB in relation to the use of these medical devices within Ireland.

ACTION OR RECOMMENDATIONS

- Check if you have these devices in your institution.
- Examine the devices to confirm that they are CE marked.
- If the device or the User Manual does not bear the CE mark, please contact the manufacturer or your supplier. The manufacturer or supplier will provide details of the necessary actions required.

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Contec Medical Systems Co., Ltd.
24 Huanghe West Road
Economic and Technical Development Zone
Qinhuangdao
Hebei Province
066004

SAFETY NOTICE

P.R.China

Contact person: Ms Vicky Liu
Telephone: +86-335-8015418
Fax: +86-335-8015418
E-mail: contecmedical@yahoo.cn

Enquiries to the European Authorized Representative should be addressed to:

Shanghai International Trading Corp., GmbH
Eiffestrasse 80
Hamburg
20537
Germany

Contact person: Mr. Jin
Telephone: +49-40-2513175
Fax: +49-40-255726
E-mail: shholding@hotmail.com