IRISH MEDICINES BOARD

Notice Information: - Advisory
13 June 2011

Part 1. Product Information

a)	Title:	Contec Devices including Pulse Oximeters, Patient monitors, Ambulatory Blood Pressure Monitors, Spirometers, Pocket fetal dopplers, B-Ultrasound Diagnostic Systems, ECG's
b)	Product Name/Type:	Contec Devices including Pulse Oximeters, Patient monitors, Ambulatory Blood Pressure Monitors, Spirometers, Pocket fetal dopplers, B-Ultrasound Diagnostic Systems, ECG's
c)	Reference:	IMB Advisory Notice: SN2011(13)
d)	Manufacturer/Supplier:	Manufacturer: Contec Medical Systems Co., Ltd. European Authorized Representative: Shanghai International Trading Corp., GmbH

Part 2. Target Audience

a)	Target Audience:	Hospital Managers / CEOs Risk Managers Clinical Directors Clinical Engineers Theatre and Nursing Staff Purchasing Managers Nursing Managers Emergency Departments Hospital personnel Medical device distributors

Part 3. Problem/Issue

a)	Problem/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.

Part 4. Background Information

a)	Background Information:	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. 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

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.

Part 5. Action to be taken

a) Action to be taken:

• 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.

Part 6. Enquiries

a)	All enquiries should be made to:	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 P.R.China Contact person: Ms Vicky Liu Telephone: +86-335-8015418 Fax: +86-335-8015418 E-mail: contecmedical@yah

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

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