

**Notice Information: - Advisory  
09 June 2011**

**Part 1. Product Information**

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

**Part 2. Target Audience**

- a) Target Audience:

**Part 3. Problem/Issue**

a) Problem/Issue:

Non-compliant patient monitors CMS7000 manufactured by Contec Medical Systems have been supplied to customers in Ireland. These monitors do not bear the CE mark as required by the medical device legislation.

#### Part 4. Background Information

a) Background Information:

The Irish Medicines Board (IMB), is advising that non-compliant patient monitors CMS7000 manufactured by Contec Medical Systems have been supplied to customers in Ireland. These monitors do not bear the CE mark as required by the medical device legislation.

The manufacturer assured the IMB that 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.

#### 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](mailto:vigilance@imb.ie)

Website: [www.imb.ie](http://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@yahoo.cn](mailto:contecmedical@yahoo.cn)

Enquiries to the Euro

E-mail: [contecmedical@yahoo.cn](mailto: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

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