IRISH MEDICINES BOARD

Notice Information: - Advisory
22 December 2010

Part 1. Product Information

a)	Title:	Counterfeit Covidien Nellcor SpO2 Durasensor® (DS-100A) sensors
b)	Product Name/Type:	Nellcor Durasensor® (DS-100A) sensors\Product Code DS-100A
c)	Reference:	SN2010(17)
d)	Manufacturer/Supplier:	Tyco Healthcare group LP Nellcor Puritan Bennett Division Pleasanton, CA USA

Part 2. Target Audience

a)	Target Audience:	General Surgeons Theatre and Nursing Staff Purchasing Managers Nursing Managers Consultant General Surgeons A&E Departments Hospital Managers / CEOs Clinical Directors Risk Managers Hospital personnel Clinical Engineers Patients

Part 3. Problem/Issue

a) Problem/Issue:

The potential supply and use of counterfeit Nellcor SpO2 Durasensor (DS-100A) sensors that are not guaranteed to meet the required standards of safety and quality, as required by the medical devices legislation.

Part 4. Background Information

a) Background Information:

Please note Diagrams referred to in this text will not display here. Please refer to attached pdf.

The Irish Medicines Board (IMB) has been alerted that counterfeit Nellcor SpO2 Durasensor (DS-100A) sensors have been found on the market in the Netherlands and Germany. The device is intended for non invasive measurement of oxygen saturation of patients over 40 kg.

The legal product is manufactured by Tyco Healthcare Group LP, Nellcor Puritan Bennett Division. To date, there is no evidence that this counterfeit product is on the Irish market but the manufacturer has confirmed that their genuine CE marked device is in general use within Ireland.

Covidien has highlighted the following differences between the counterfeit devices and the genuine devices:

1. Sensor- The authentic Covidien product has shiny finish on the device housing (figure 1) whereas the counterfeit product has an opaque finish (figure 2)

2. Feather of the sensor (can be seen when sensor is opened) - The authentic Covidien product has one winding of the feather (figure 3) whereas the counterfeit product has three windings of the feather (figure 4)

3. Optical part of the sensor (can be seen if sensor is opened) - The authentic Covidien product has two visible cables in red and black (figure 5) whereas the counterfeit product has no visible cables (figure 6)

4. Carton Top - The authentic Covidien product does not have the REF symbol printed in Bold on the carton top label (figure 7) whereas the counterfeit product has the REF symbol printed in Bold (figure 8) 5. Carton bottom -

5. Carton bottom - The authentic Covidien product has a rounded press cut in the carton round (figure 9) whereas the counterfeit product as angular press cut in the carton (figure 10)

6. Carton bottom - The counterfeit product has additional labels where “Handheld Pulse Oximeter-Oxygen Sensor” is printed on and additional bill of materials (figure 10), as can be seen on picture 10 the additional labels indicate that the sensors were manufactured for use out of Europe and the European Union as there are none of the European languages on there.

7. Carton bottom - The counterfeit product has a darker background colour (figure 9) than the authentic product (figure 10).

The exact risks associated with the use of the counterfeit product are unknown. As the counterfeit product was not manufactured by Covidien they cannot confirm the performance, mechanical properties, biocompatibility or sterility of the product.

The manufacturer, Tyco Healthcare Group, Nellcor Puritan Bennett Division, recommends that all products are purchased directly from Covidien or an authorised distributor.

Covidien can be contacted by calling Deirdre O’Connor at 087 816 85 19 or Mark Gray at 087 653 8087 if you have medical questions regarding suspected counterfeit product.

Part 5. Action to be taken

a)	Action to be taken:	The IMB advises that: • All products in your possession should be checked using the details above to assess whether the product is genuine or counterfeit. • If from your assessment you determine or suspect that you have product that is counterfeit, quarantine the product to ensure it will not be used and contact your local Covidien representative, who will be able to confirm if the product is authentic. • If you identify that you have product that is counterfeit you should return any such affected product in your possession to the local Covidien representative and inform the IMB.

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 should be addressed to: Local Covidien Office: Deirdre O'Connor at: 087 8168519 Mark Gray at: 087 6538087 Covidien Ireland Block G, 1st Floor Loughlinstown Dublin Please click here to download a pdf version of the safety Notice

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