IRISH MEDICINES BOARD
SAFETY NOTICE

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Counterfeit Covidien Nellcor SpO2 Durasensor® (DS-100A) sensors

IMB Safety Notice: SN2011(01)
Circulation Date: 21 January 2011

PRODUCT NAME: **Nellcor Durasensor® (DS-100A) sensors**

PRODUCT CODE: **DS-100A**

MANUFACTURER:
Tyco Healthcare group LP
Nellcor Puritan Bennett Division
Pleasanton, CA USA

TARGET GROUPS
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

ISSUE
The 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.

BACKGROUND
In December 2010 the Irish Medicines Board (IMB) were informed that counterfeit Nellcor SpO2 Durasensor (DS-100A) sensors had been found on the market in the Netherlands and Germany. Following distribution of the IMB Safety Notice SN2010(17) the IMB has received confirmation that the counterfeit Nellcor SpO2 Durasensor (DS-100A) sensors have been supplied to a number of hospitals in Ireland. The legal product is manufactured by Tyco Healthcare Group LP, Nellcor Puritan Bennett Division.

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The IMB is distributing this updated Safety Notice to remind users of the Nellcor SpO2 Durasensor (DS-100A) sensors to carry out an inspection of all devices in stock, as per the instructions provided below by Covidien, to confirm their authenticity.

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)

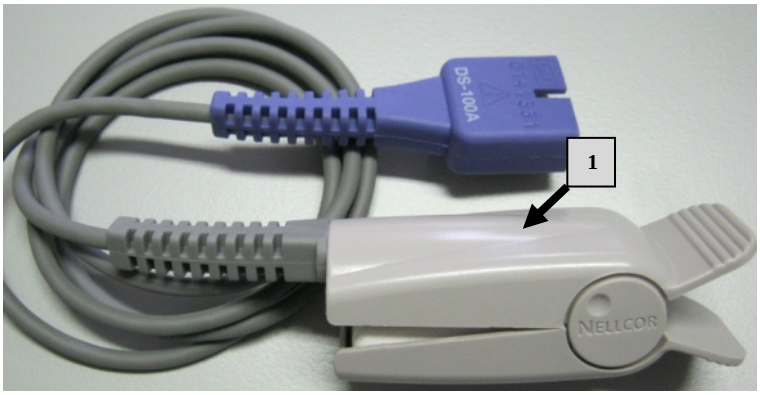

Figure 1 Authentic Product with shiny finish

Figure 2 Counterfeit Product with dull/matt finish

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)

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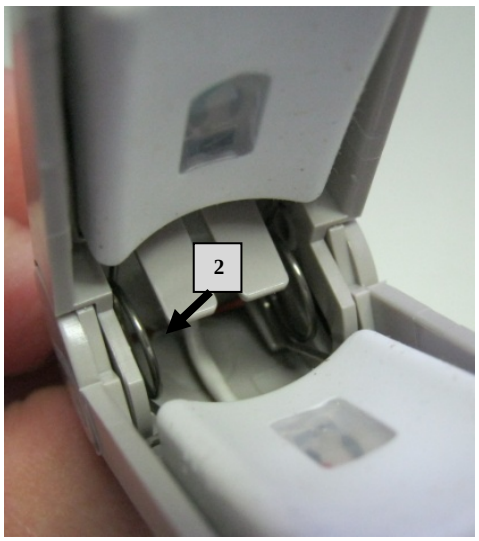

Figure 3 Authentic product with one winding of the feather

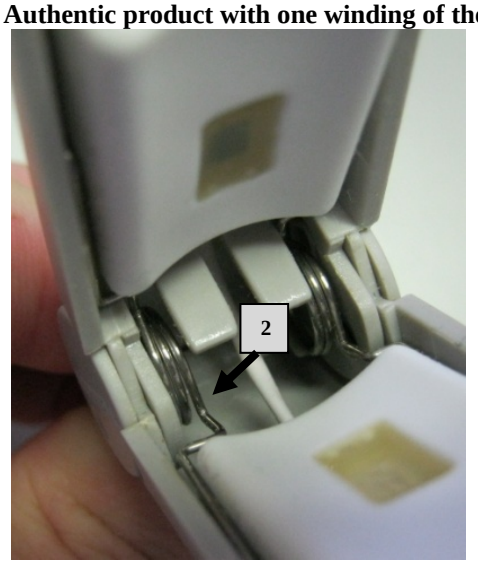

Figure 4 Counterfeit product with 3 windings of the feather

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)

Figure 5 Authentic product with two visible cables in red and black

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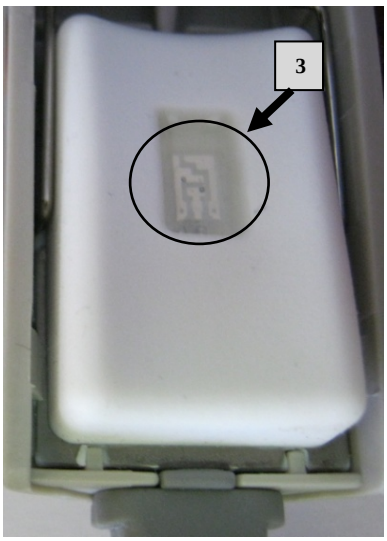

Figure 6 Counterfeit product with no visible cables

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)

Figure 7 Authentic product does not have the REF symbol printed in Bold

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Figure 8 Counterfeit product does has the REF symbol printed in Bold

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).

Figure 9 Authentic product

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Figure 10 Counterfeit product

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. Functional tests carried out by Covidien showed the counterfeit devices partially failed to provide SpO2 readings, when tested with OxiMax™/ Nellcor monitors. These sensors can be used with a range of monitors.

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.

ACTIONS OR RECOMMENDATIONS

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 identify, locate and quarantine all product to ensure it will not be used.
- If you identify that you have product that is counterfeit you should submit the information detailed in Appendix I to the IMB (enforcement@imb.ie and vigilance@imb.ie). On receipt of this information the IMB will contact you to advise what further course of action is required.

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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 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

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APPENDIX I
Counterfeit Nellcor SpO2 Durasensor (DS-100A) Sensors Information

Where counterfeit Nellcor SpO2 Durasensor (DS-100A) sensors have been identified at your facility the IMB request that you provide the following information to the IMB (enforcement@imb.ie or vigilance@imb.ie):

- Name, position and contact details of submitter.
- Name and contact details of your facility.
- Number of counterfeit Nellcor SpO2 Durasensor (DS-100A) sensors supplied.
- Number of counterfeit Nellcor SpO2 Durasensor (DS-100A) identified and current location.
- Name and contact details of supplier of counterfeit Nellcor SpO2 Durasensor (DS-100A) sensors.
- Date of supply of counterfeit Nellcor SpO2 Durasensor (DS-100A).
- Have any adverse incidents relating to counterfeit Nellcor SpO2 Durasensor (DS-100A) been reported? If so, please provide details.