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NOTICE

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

IMB Safety Notice: SN2010(17)

Circulation Date: 22 December 2010

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 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.

BACKGROUND

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.

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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)

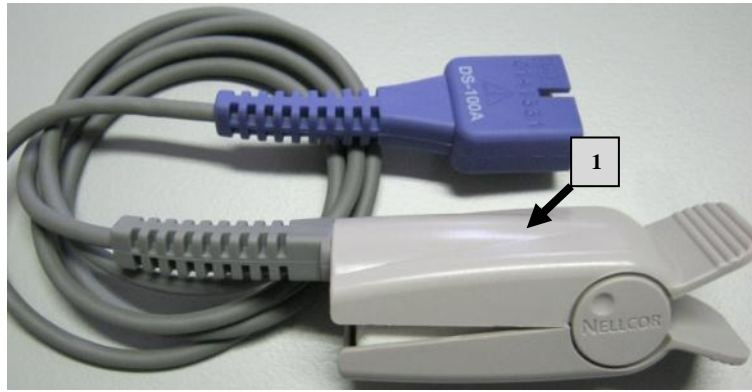


Figure 1 Authentic Product with shiny finish

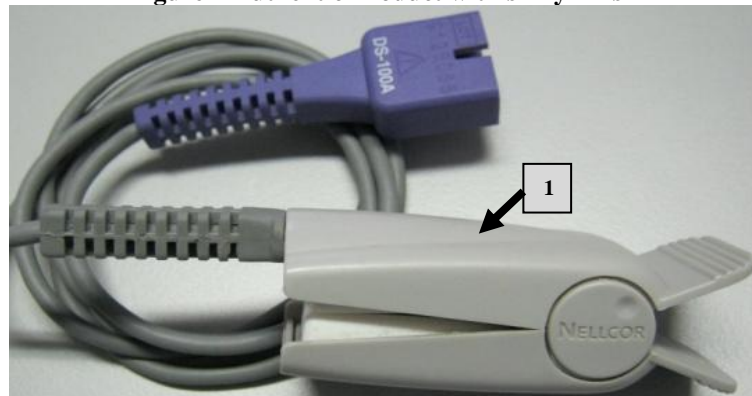


Figure 2 Counterfeit Product with dull/mat finish

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)

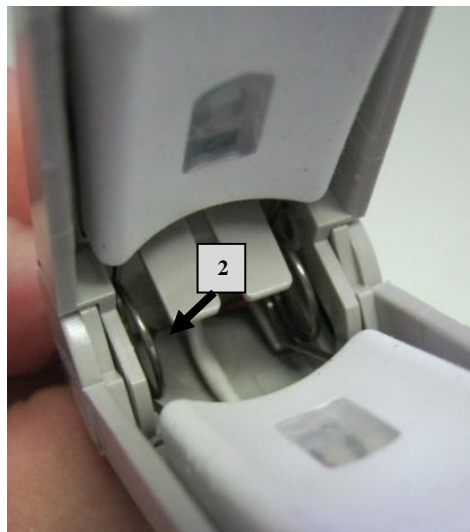


Figure 3 Authentic product with one winding of the feather

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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



Figure 6 Counterfeit product with no visible cables

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- 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)

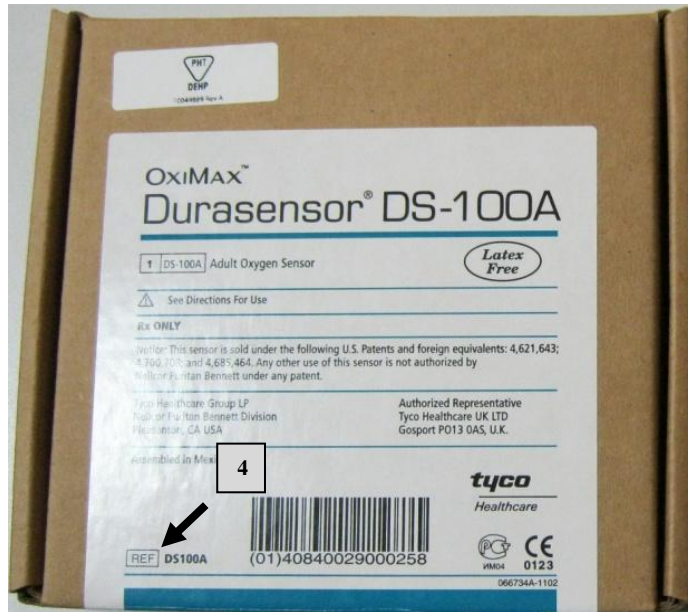


Figure 7 Authentic product does not have the REF symbol printed in Bold

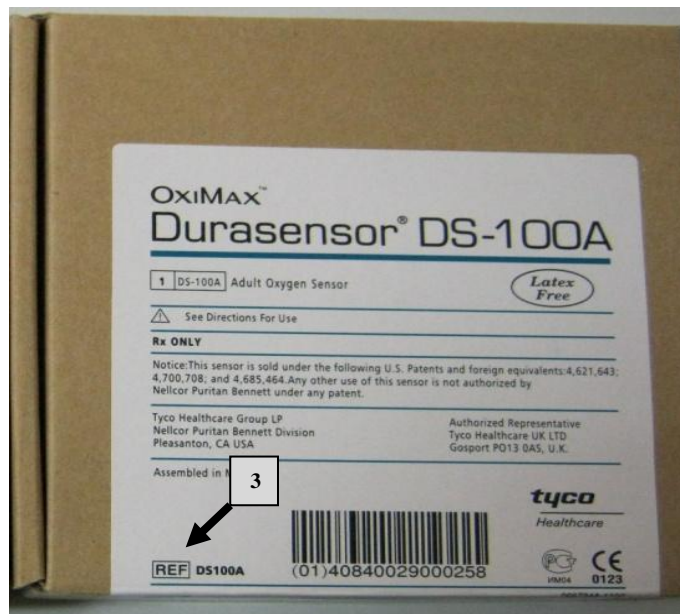


Figure 8 Counterfeit product does has the REF symbol printed in Bold

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

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Figure 9 Authentic product does not have the REF symbol printed in Bold



Figure 10 Counterfeit product does has the REF symbol printed in Bold

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, EES, 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.

部件名称	有害有害物质或元素					
	铅 (Pb)	汞 (Hg)	镉 (Cd)	六价铬 (Cr6+)	多溴联苯 (PBB)	多溴二苯醚 (PBDE)
Cable, assy	X	O	X	O	O	O
Housing assy, bottom/Solder	X	O	O	O	O	O
Housing assy, top/Solder	X	O	O	O	O	O

O: 表示该有害物质在该部件所有均质材料中的含量均在SJ/T11363-2006标准规定的限量要求以下
X: 表示该有害物质至少在该部件的某一均质材料中的含量超出SJ/T11363-2006标准规定的限量要求
(企业可在此处, 根据实际情况对上表中打“x”的技术原因进行进一步说明)

DS100A	DURASENSOR, ADULT, DIGIT Reusable Sensors
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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, 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.

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