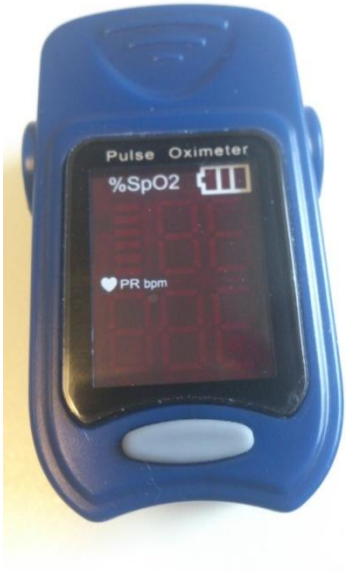
Safety Notice
Medical Devices

IRISH MEDICINES BOARD

Pulse Oximeter Models FS10A and FS20A



Priority 1 – For Immediate Action

IMB Safety Notice: SN2014(28) **Issue Date: 25 June 2014**

MANUFACTURER / SUPPLIER	IMB CASE REFERENCE
Inappropriately indicated on label as: MEDI GmbH & Co KG	CP19356

ISSUE

The supply of non-compliant **Pulse Oximeters** inappropriately CE marked claiming compliance with the medical device legislation that are not guaranteed to meet the required standards of safety and quality

ACTION OR RECOMMENDATIONS

The Irish Medicines Board (IMB) advises that :

(1) All stock of pulse oximeters should be checked to identify non-compliant devices using the details in this Safety Notice

(2) If from your assessment you determine or suspect that you have the non-compliant devices in stock, locate and quarantine all devices to ensure they will not be used.

(3) If you identify that you have any of the non-compliant devices identified in this Safety Notice contact the IMB immediately at medicaldevices@imb.ie

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

BACKGROUND

The IMB was recently notified of the supply of non-compliant pulse oximeters to the Irish market that inappropriately bear the CE mark on their labeling claiming compliance with the medical device Directive 93/42/EEC.

The product is labeled as **Pulse Oximeter Model No FS10A** and the manufacturer is indicated on the labeling as **MEDI GmbH & Co. KG** Medicusstr. 1 95448 Bayreuth, Germany. The packaging and Instructions for Use supplied with the product also reference Model FS20A. Please refer to the images below for reference.

The manufacturer MEDI GmbH & Co. KG that is indicated on the product as the manufacturer of the pulse oximeter confirmed that they have never manufactured or sold the pulse oximeter model FS10A or FS20A. The Notified Body indicated on the labeling also confirmed that they have never issued a CE certification for this device to the manufacturer MEDI GmbH & Co. KG.

Figure 1: Image of Pulse Oximeter device and labelling

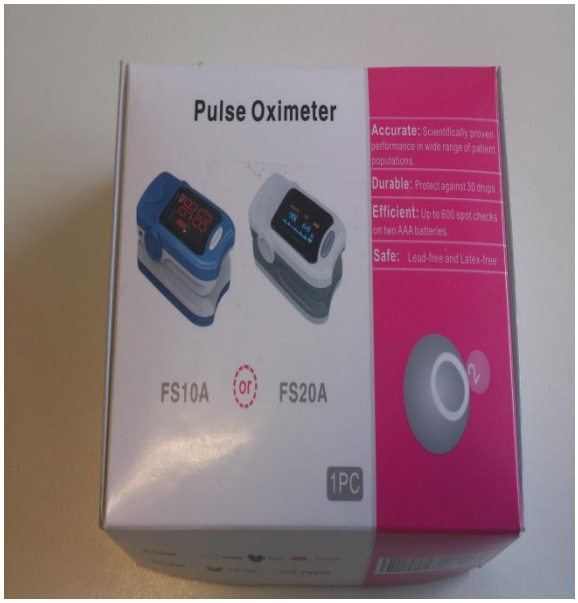


Figure 1: Image of Pulse Oximeter device outer packaging

Based on this data, the IMB considers all Pulse Oximeter Model FS10A and FS20A that indicate the manufacturer to be MEDI GmbH & Co KG on the product labeling to be non-compliant with the medical device Directive 93/42/EEC. The CE mark on the labeling has been unduly placed on these devices.

These devices were found at a local logistics company in Ireland and the shipment originated in China, though the source could not be confirmed.

The safety and quality of inappropriately CE marked medical devices cannot be guaranteed as they may not be manufactured to the required standards or conform to the requirements of the medical device legislation.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

MEDI GmbH & Co. KG	Telephone:	0921/912 1315
Medicusstr. 1	Fax:	0921/912 8315
95448 Bayreuth,	E-mail:	S.Buchner@medi.de
Germany	Website:	www.medi.de

IMB CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Irish Medicines Board	Telephone:	+353-1-6764971
Human Products Monitoring	Fax:	+353-1-6344033
Kevin O'Malley House	E-mail:	vigilance@imb.ie
Earlsfort Centre	Website:	www.imb.ie
Earlsfort Terrace		
Dublin 2		