

27th October 2014

## **URGENT FIELD SAFETY NOTICE – PRODUCT RECALL**

### **Medicina Low Profile Gastrostomy Button (MBXX/YY)**

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Attention: All Nursing, Medical, and Technical staff using this product;

#### **Reason for the Recall Notice**

The safety and performance of these devices have not been properly evaluated and so the CE marking of the device is not valid. We therefore advise that the product is recalled from the market.

#### **Details of Device**

Medicina Low Profile Gastrostomy Button MBXX/YY where XX is the size of the button in French gauge and YY is the length of the button in centimetres.



All Batch/lot numbers and sizes of the Medicina Low Profile Gastrostomy Button to be recalled, have supplied between May 2012 to May 2014

#### **Action to be taken**

If any you hold any stock of Medicina Low Profile Gastrostomy Buttons we advise that the following actions are taken:

1. Contact Medicina using the details below and either return to Medicina or Medicina will make arrangements for collection.

**Contact**

Carol Cole  
Quality Assurance  
Unit 2  
Rivington View Business Park  
Station Road  
Blackrod  
Bolton  
BL6 5BN  
Email: [carol@medicina.co.uk](mailto:carol@medicina.co.uk)

Tel: +44 (0) 1204 695050

Fax: +44 (0) 1204 697755

Medicina confirms that this notice has been notified to the appropriate Regulatory Agency.



**FAX BACK FORM**

**Recall Notice – October 2014**

**MBXX/YY Medicina Low Profile Gastrostomy Buttons**

**Please fax back to:** Carol Cole, Quality Assurance, and **Fax:** +44 (0) 1204 697755

We hereby certify that we have received, read, and distributed this Product Recall Notice to anyone it may concern within our organisation.

Hospital/Depot:

Name:

Department:

Function:

Date:

Print name.

Signature: