

# MEDICAL DEVICE SAFETY NOTICE

## Illegally CE Marked Medical Devices

IMB Safety Notice: SN2005(04)

### MANUFACTURER/SUPPLIER

Various (see table below)

### TARGET GROUPS

Health Services Executive  
Chief Executive Officers  
Risk Managers  
Purchasing Managers  
Medical, Dental & Nursing Staff  
Operating Theatres  
Accident & Emergency  
Intensive Care Units  
Coronary Care Units  
Medical Physics  
Ambulance Staff & Paramedics  
Resuscitation Officers  
General Practitioners  
Practice Nurses  
Dental Practitioners  
Radiologists / Radiographers  
Ophthalmologists  
Medical Laboratory Managers

### ISSUE

Medical devices may have been placed on the European market bearing an illegal CE mark.

### BACKGROUND

The Irish Medicines Board (IMB) has been informed by the Norwegian Competent Authority that medical devices illegally bearing the marking "CE 0434" may have been placed on the European market by manufacturers specified in the table below.

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NOTICE**

The Norwegian Notified Body Det Norske Veritas Region Norge AS (DNV) has discovered the existence of CE certificates of conformity that have not been issued by them i.e. there may be medical devices on the European market bearing their identification number “CE 0434” for which they have not carried out conformity assessment in line with medical devices legislation

The manufacturers who forged the false certificates have been identified by the Notified Body and have been ordered to withdraw the certificates immediately.

The manufacturers in question and their product ranges are as follows:

| <b>Manufacturer</b>   | <b>Product Type</b>   |
|---|---|
| Kashmir Surgical Workes,<br>India                               | Ophthalmic Equipment  |
| Plantech Medical System Private<br>Limited, Ahmedabad, India    | Ophthalmic Equipment  |
| Pembekalam Perubatan,<br>Malaysia                               | Disposable Medical Devices  |
| MEK Co. Limited,<br>Korea                                       | Patient Monitoring Devices  |
| Skylark Device & Systems Co. Limited<br>(country unknown)       | Diagnostics Systems   |
| Aygün Cerrahi Aletler San. Ve Tic.<br>A. S., Turkey             | Container System  |
| Sasurel (Pty) Limited t/a Clinisut,<br>Republic of South Africa | No Information  |
| Shanghai Changujun Import & Export<br>Co. Limited, China        | Gauze Swabs, Gauze Rolls,<br>Lap. Sponges                           |
| Imago Radiology s.r.l.,<br>Italy                                | X-ray Generators  |
| PAK Marten International,<br>Sialkot, Pakistan                  | Surgical, Dental, Veterinary<br>Instruments & Scissors all<br>sorts |
| Varimex, Polish Company Foreign<br>Trade, Warszawa, Poland      | Medical Equipments<br>Coagulator                                    |

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**NOTICE**

As the medical devices in question have not been verified against CE marking requirements the safety, quality and performance of these products cannot be guaranteed.

### **ACTION OR RECOMMENDATIONS**

The IMB advises that you:

- Check if you have any of the above medical devices from the manufacturers identified bearing the marking “CE 0434” in your possession.
- If you identify these products you should quarantine the stock involved and contact the Medical Devices Department of the IMB immediately.
- Provide any details in relation to the source of the products to the IMB.

### **ENQUIRIES**

If you have any enquiries relating to the above you may contact Máiréad Finucane at the Medical Devices Department of the Irish Medicines Board at:

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Kevin O’Malley House  
Irish Medicines Board  
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Fax: +353-1-6344033  
Email: [medicaldevices@imb.ie](mailto:medicaldevices@imb.ie)  
Website: [www.imb.ie](http://www.imb.ie)

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