

# MEDICAL DEVICE SAFETY NOTICE

## URGENT PRODUCT RECALL IMB Safety Notice: SN2005(03)

### Product Name: “Tulip” Condoms

#### TARGET GROUPS

Consumer Public

#### ISSUES

- These products do not carry a CE mark.
- The labelling of the condoms is in the Chinese language and not in the English language as required by the national medical devices regulations.

#### BACKGROUND

It has come to the attention of the Irish Medicines Board (IMB) that a brand of condoms bearing the “Tulip” brand name has been illegally imported into Ireland and has been placed on the Irish market. These products have been sold to the public by a vendor on Moore Street in Dublin.

These products are classified as medical devices under the Medical Devices Directive 93/42/EEC, Article 1, 2(a) and the related S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations, 1994. These condoms **do not carry a CE mark** in line with the legislation. In order to place a medical device on the Irish market the manufacturer / authorised representative is required to CE mark the product.

As the condoms have not been verified against CE marking requirements it cannot be confirmed if these condoms provide an effective barrier and therefore they cannot be guaranteed to prevent transmission of sexually transmitted diseases or work as an effective means of contraception.

A recall of these condoms is underway.

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NOTICE

## **ACTION OR RECOMMENDATIONS**

The IMB advises that you:

- Check if you have “Tulip” condoms in your possession.
- If you have identified that you have these products you should dispose of these products immediately.
- If you think you may have used these condoms and have any health concerns, please consult your General Practitioner for their advice.

## **ENQUIRIES**

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

Irish Medicines Board  
Medical Devices Department  
Kevin O'Malley House  
Earlsfort Centre  
Earlsfort Terrace  
Dublin 2

Telephone: 01-6764971  
Fax: 01-6344033  
Email: [medicaldevices@imb.ie](mailto:medicaldevices@imb.ie)

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