



S
A
F
E
T
Y

NOTICE

Explorer Loop 4 Wheeled Rollator

IMB Safety Notice: SN2011(14)

Circulation Date: 15 June 2011

MANUFACTURER/SUPPLIER

Manufacturer: Jiangsu Kongung Medical Equipment Co. Limited, China
Distributor: Murray's Medical, Dublin

TARGET GROUPS

General public
Hospital CEO's
Procurement Managers
HSE Offices
Community Care Centres
Physiotherapists
Pharmacies

ISSUE

Non-compliant Explorer Loop 4 Wheeled Rollators have been supplied to the Irish market. These rollators are not CE marked, as required by the medical devices legislation.

BACKGROUND

The IMB is advising that non-compliant Explorer Loop 4 Wheeled Rollators have been placed on the Irish market.

As these rollators are not CE marked, it cannot be guaranteed that these products have been manufactured to the appropriate standards and therefore may not reach the required standards of safety and quality, as required by the European medical device legislation.

As a precautionary measure, the IMB advises all consumers to stop using these Explorer Loop 4 Wheeled Rollators.

ACTION OR RECOMMENDATIONS

Consumers should check their rollators to determine if their device is branded an Explorer Loop 4 Wheeled Rollator.

If you find that you have one of these products, discontinue use immediately and contact Murray's Medical to obtain an alternative product.

S A F E T Y NOTICE

ENQUIRIES

Enquiries to the Irish distributor should be addressed to:

Ms. Sarah O'Loughlin
Murray's Medical Equipment Limited
Airton Park
Airton Road
Tallaght
Dublin 24

Telephone: +353-1- 866 3310
Email: sarah.oloughlin@murrays.ie

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

Human Products Monitoring
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