

Notice Information: - Recall 15 June 2011

Part 1. Product Information

- a) Title: Explorer Loop 4 Wheeled Rollator
- b) Product Name/Type: Explorer Loop 4 Wheeled Rollator
- c) Reference: SN2011(14)
- d) Manufacturer/Supplier: Manufacturer: Jiangsu Kongung Medical Equipment Co. Limited, China
Distributor: Murray's Medical, Dublin

Part 2. Target Audience

- a) Target Audience:
- General public
 - Hospital CEO's
 - Procurement Managers
 - HSE Offices
 - Community Care Centres
 - Physiotherapists
 - Pharmacies

Part 3. Problem/Issue

- a) Problem/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.

Part 4. Background Information

a) Background Information:

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.

Part 5. Action to be taken

a) Action to be taken:

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.

Part 6. Enquiries

- a) All enquiries should be made to:

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

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