IRISH MEDICINES BOARD

Notice Information: - Advisory
23 April 2012

Part 1. Product Information

a)	Title:	G&S Smirthwaite Samba Chair
b)	Product Name/Type:	G&S Smirthwaite Samba Chair
c)	Reference:	SN2012(04)
d)	Manufacturer/Supplier:	G&S Smirthwaite Ltd.

Part 2. Target Audience

a) Target Audience:

- General public
- Hospital CEOs
- Risk Managers
- Procurement Managers
- Loan Store Managers
- HSE Offices
- Community Care Centres
- Occupational Therapists
- Community Care Managers
- Community Therapists
- Health Visitors
- Carers
- Educational Establishments

Part 3. Problem/Issue

a)	Problem/Issue:	G&S Smirthwaite Ltd. issued a field safety notice (FSN) highlighting to users of the Samba Chair that for certain product code / serial number combinations, the lever operating the chair 'Tilt in Space' function (TIS) may not freely engage into the notch in the safety catch. The Irish Medicines Board (IMB) is aware that there has been difficulty in locating all devices in Ireland affected by this field safety corrective action.

Part 4. Background Information

a)	Background Information:	The safety catch is designed to prevent accidental operation of the TIS lever. The TIS lever is located on the left hand side of the Samba chair and has a red button for identification. The TIS mechanism features a safety catch that is designed to prevent accidental operation of the lever. When the lever is operated and released, it should always return to a 'park' position, as shown in the attached FSN. The FSN for this issue, TB 2011-2/1, was circulated to the Irish market by O'Neill Healthcare in March 2011. O'Neill Healthcare is no longer the distributor for this product in Ireland and all queries relating to this action should be addressed to G&S Smirthwaite Ltd.

Part 5. Action to be taken

a)	Action to be taken:	The IMB advises that users ensure the appropriate personnel are made aware of this notice and follow the manufacturer's recommendations in the attached FSN.

Part 6. Enquiries

a) All enquiries should be made to:

Enquiries to the manufacturer should be addressed to:

Mr. Richard Snape

G&S Smirthwaite Ltd.

17 Wentworth Road

Heathfield

Newton Abbot

Devon, England

TQ12 6TL

Telephone: +44 1626 835552

Email: enquiries@smirthwaite.co.uk

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

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 Please click here to download a PDF version of this Safety

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Please click here to download a copy of the Field Safety Notice