الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المخزونات: 85/29
رقم الصادر: 1208/2012
بيروت، في: 0 - آب 2012

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Folio dress gown Comfort Basic

الجهاز الصحي بالمناسبة:
- Folio dress gown Comfort Basic
- Trade Mark: Paul Hartmann
- Local Representative:

بناءً على التوصية الصادرة عن الشركة المصنعة والتي تشير إلى وجود خلل في عملية تغليف
الصنف المذكور أعلاه مما قد يؤثر على فعالية التعقيم، نرجو منكم تعميم هذه النشرة على جميع
المستشفيات المعنية.

مرفق ربط:
- التوصية الصادرة عن الشركة المصنعة
- دائرَة البرامج والمشاريع
- المستشفيات الحكومية
- المخزونات

مدير عام الصحة

Dr. Wadad Qaddouri
Urgent Field Safety Notice – Product Recall

Dear Dr. Sulaiman,

Today we have to inform you about the attached Field Safety Notice (FSN).

We kindly ask you to confirm the receipt of this following FSN and initiate the necessary steps to recall the products as described. For the required confirmations please use the attached response form.

Please be aware that you are responsible to report this issue to the competent authorities in your country. We kindly request you to send us a copy of your report to the authorities latest until July 31, 2012.

For questions or further information, please do not hesitate to contact us.

Kind regards,

PAUL HARTMANN Middle East FZE

[Signatures]

Alexander Burger
Managing Director

Dr. Fatima Zaid Abu Zanat
Regional Regulatory Affairs Coordinator

PAUL HARTMANN Middle East FZE
Free Zone Establishment
Dubai Airports Free Zone
P.O.Box 59525
Dubai
United Arab Emirates

Telephone: +971 4 2998996
Telefax: +971 4 2998998

www.hartmann.info

HARTMANN helps healing.

Fees are imposed for the use of this service.

Terms and Conditions

Page 1 of 5
Urgent Field Safety Notice (Product Recall)

Corrective Action: Recall of various sterile surgical gowns and isolation gowns under the brand Felpodress as per attachment 1

July 23, 2012

Sender: PAUL HARTMANN Middle East FZE
        Dubai Airport Free Zone
        West Wing 3, Office No. 222
        P.O. Box 54925
        Dubai
        United Arab Emirates

Recipient: Abdulrehaman Alyosaibi G.T.C.
            Dr. Mohammed Sulaiman
            King Abdul Aziz Avenue, Old Airport Road
            Al Gosaibi Building
            P.O. Box 215
            Riyadh 11411
            Saudi Arabia

Affected product:
Complete list as per attachment 1

Description of the problem:
A quality inspection revealed the individual occurrence of micro-holes in a number of blister packs (sterile packaging) containing sterile surgical gowns and isolation gowns. These micro-holes are unlikely to be detected through visual inspection. As a result, the sterility of affected products may be compromised.

As we are unable to reliably exclude a risk of individual occurrence of micro-holes in these products, we have decided to take all necessary precautions and recall the potentially affected references. For references and details to Lot number please refer to attachment 1.

Advice on action:
Please examine your inventory and do not use the affected products any longer.
We kindly ask you to confirm the receipt of this notification and report back volume of affected stock by returning the below attached form (attachment 2).

Upon receipt of your response (attachment 1 & 2) we will contact you to discuss the details to collect the articles from your warehouse.

Your usual HARTMANN sales representative or customer service contact is happy to assist you with any further inquiries in this matter. In addition, you may contact us directly via a dedicated hotline:

Phone: +971 4 2996996
Fax: +971 4 2996998
Email: fatma.z.abuzanat@hartmann.info
Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected products have been transferred to. Therefore please take adequate measures.

We earnestly regret any inconvenience caused by this measure.

Dubai, July 23, 2012
PAUL HARTMANN Middle East FZE

[Signature]

Alexander Beugel
Managing Director

[Signature]

Dr. Fatima Zaid Abu Zanat
Regional Regulatory Affairs Coordinator

Attachment

1. Product list
2. Response form