



رقم المحفوظات: ٣٨١٢٥
رقم الصادر: ١٣/١/٢٠١٢
بيروت، في: ١٥ شباط ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة مستحضر طبي
Sterile gauze products

الجهاز المعنى بالمتابعة:

- Sterile gauze products
- Trade Mark: PAUL HARTMANN
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خطأ في التوضيب مما يؤثر على جودة الصنف المذكور أعلاه لجهة تعقيمه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

Urgent Field Safety Notice (Product Recall)

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

July 23, 2012

Sender: PAUL HARTMANN AG
Paul-Hartmann-Str. 12
89522 Heidenheim

Recipient: „affiliate / authorized distributor“

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 blisters (sterile packaging) containing sterile surgical gowns and isolation gowns. The 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.

Advise on action:

Please examine your inventory, don't use the affected product any longer, quarantine it and collect the goods locally until further notice.

Your contact for further information is [REDACTED] telephone: (+49) 7321 – 36 1430. Please complete and return the attached response forms to him.

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. A template for a customer letter is enclosed. Customers are requested to return all stock to the local HARTMANN affiliates / authorised distributor.

We do require your written confirmation of implementation and closing of the corrective action. We will keep you informed about further actions.

This Field Safety Notice has been submitted to the Competent Authorities of the concerned countries within the European Economic Area (EEA). In countries outside the EEA the respective affiliate / authorized distributor is responsible to fulfil the relevant medical reporting duties to their respective competent authority.

Heidenheim, July 23, 2012
PAUL HARTMANN AG

[REDACTED] [REDACTED]

Attachement:

1. Product List
2. Response form 1 & 2

Attachement 2:

„affiliate / authorized distributor adress“

Response Form 1 [REDACTED] **via fax or email**

[REDACTED] MANN AG

[REDACTED]
Fax: +49-7321-36-2430
[REDACTED]

Recall of various sterile surgical gowns and isolation gowns

We hereby confirm receipt of the field safety notice issued by PAUL HARTMANN AG dated July 23, 2012 and transmission to all those who need to be aware within our organisation or to any organisation / customer where the potentially affected products have been transferred and that all our stocks of the affected lots are blocked.

Date, Stamp and Signature

Additional confirmation for outside EEC countries *(cross-out, if not applicable)*

We further confirm fulfilment of all legally required reporting duties to local competent authorities. A copy of submitted documents and confirmation of receipt of the competent authority is attached.

Date, Stamp and Signature

„affiliate / authorized distributor adress“

Response Form 2 [REDACTED] **via fax or email**

[REDACTED] MANN AG

Fax: +49-7321-36-2430
[REDACTED]

Recall of various sterile surgical gowns and isolation gowns

We hereby confirm that the corrective action has been closed.

Examination of inventory:

“country individual exchange of stock data”

(Please tick appropriate box)

- Total quantity was returned to PAUL HARTMANN AG.
- Total quantity is quarantined in our warehouse until further notice from PAUL HARTMANN AG.

No further affected products are therefore on stock.

Date, Stamp and Signature

Anlage 1 / attachment 1: Artikelliste / product list

DE

Handelsname / trade name	REF (Artikelnr.) / REF (article no.) x = 0 - 9 (nicht auf Sterilverpackung / not on sterile packaging)	Artikelbezeichnung / article description	betroffene Lot-Nr. / affected lot no. alle LOT mit der Ziffernfolge / all LOT with digit sequence (x: betriebsinterne Ziffer und hier ohne Belang) (x: internal digit without relevance)
Foliodress gown Comfort Basic	992172x	FoliodressGown Comf Basic L st krepp P28	xxxx0100x
Foliodress gown Comfort Basic	992173x	FoliodressGown ComfBasic XL st krepp P28	xxxx0100x
Foliodress gown Comfort Perfect	992182x	Foliodress Gown Comf Perfect L st P28	xxxx0100x
Foliodress gown Comfort Perfect	992183x	Foliodress gown Comf Perf C&T XL P28	xxxx0100x
Foliodress gown Comfort Perfect	992184x	Foliodress Gown Comf Perfect XXL CT P28	xxxx0100x
Foliodress gown Comfort Perfect	992186x	Foliodress gown Perfect L P&G P32	xxxx0100x
Foliodress gown Comfort Perfect	992187x	Foliodress Gown Comf Perfect XL P&G P28	xxxx0100x
Foliodress gown Comfort Special	992192x	Foliodress Gown Comf. special L C&T P28	xxxx0100x
Foliodress gown Comfort Special	992193x	Foliodress Gown Comf Special XL C&T P28	xxxx0100x
Foliodress gown Comfort Special	992194x	Foliodr. Gown Comf. special XXL C&T P28	xxxx0100x
Foliodress gown Comfort Special	992195x	FdressGown ComfSpecial XXLL st krepp P24	xxxx0100x
Foliodress gown Comfort Special	992196x	Foliodr. Gown Comfort special L P&G P28	xxxx0100x
Foliodress gown Comfort Special	992197x	Foliodress Gown Comf Spec XL P&G P28	xxxx0100x
Foliodress gown Comfort Special Classic	992164x	Foliodr. Comf. special L classic C&T P28	xxxx0100x
Foliodress gown Comfort Special Classic	992165x	Foliod. Comf. special XL classic C&T P28	xxxx0100x
Foliodress gown Comfort Special Classic	992166x	Foliod.Comf. special XXL classic C&T P28	xxxx0100x
Foliodress gown Comfort Urology	992180x	Foliodress Urology st Gown L P28	xxxx0100x
Foliodress gown Comfort Urology	992181x	Foliodress Urology st Gown XL P28	xxxx0100x
Foliodress gown Protect Open Back	992178x	Foliodress Protect Open Back L st P36	xxxx0100x
Foliodress gown Protect Open Back	992179x	Foliodress Protect Open Back XL st P36	xxxx0100x
Foliodress gown Protect Reinforced	992147x	Foliodress Protect standard XXL st P28	xxxx0100x
Foliodress gown Protect Reinforced	992154x	Foliodress Protect verstaerkt M st P36	xxxx0100x
Foliodress gown Protect Reinforced	992155x	Foliodress Protect verstaerkt L st P28	xxxx0100x
Foliodress gown Protect Reinforced	992156x	Foliodress Protect verstaerkt XL st P28	xxxx0100x
Foliodress gown Protect Reinforced	992157x	Foliodress Protect verstaerkt XXL st P28	xxxx0100x
Foliodress gown Protect Standard	992144x	Foliodress Protect standard M st P36	xxxx0100x
Foliodress gown Protect Standard	992145x	Foliodress Protect standard L st P28	xxxx0100x
Foliodress gown Protect Standard	992146x	Foliodress Protect standard XL st P28	xxxx0100x
Foliodress S Isolation Gown	992167x	Foliodress S Besuchermantel st blau P48	xxxx0100x
Foliodress S Isolation Gown	992168x	Foliodress S Besuchermantel st weiß P44	xxxx0100x