REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٥٠/٧٧
رقم الصادر:
بيروت، في ١٢/١/٢٠١٣
١ - تشرين الثاني ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Breathing Circuit, Universal Flex 2

الجهاز المعنى بالمتابعة:

- Breathing Circuit, Universal Flex 2
- Trade Mark: King Systems Corp.
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA
والذي يشير الى وجود خطأ في محتوى الملصق للصنف المذكور أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

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See Related Information[21]

Class 1 Recall
Universal Flex2 Breathing Circuit

Date Posted	September 27, 2013
Recall Number	Z-2272-2013
Product	Universal Flex2 Breathing Circuit Class I 510(k) Exempt An anesthesia breathing circuit is a device that is intended to administer medical gases to a patient during anesthesia. It provides both an inhalation and exhalation route and may include a connector, adaptor, and Y-piece.
Code Information	Part Number DF4110-61 Lot Number I063N
Recalling Firm/ Manufacturer	King Systems Corp. 15011 Herriman Blvd Noblesville, Indiana 46060-4253
Consumer Instructions	Contact the recalling firm for information
Reason for Recall	King Systems received a customer complaint indicating that the customer had ordered a breathing circuit with a Latex breathing bag. The product they received contained a Latex breathing bag, but was labeled as non-latex.
Action	Ambu, Inc. sent a letter dated June 24, 2013, informing the customer that they have decided to discontinue the manufacture and sales of the King Systems latex breathing bags and to conver all customers to their King Systems latex-free breathing bags. The customer was advised to adjust their inventories accordingly and transition to the latex free part number as their inventory levels reach their minimums. For questions the customer was advised to call 317-403-8677. For questions regarding this recall call 317-776-6823.
Quantity in Commerce	1 case; 40 units
Distribution	Nationwide Distribution - NE only.

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14. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
15. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
17. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
18. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
19. /scripts/cdrh/cfdocs/cfClia/Search.cfm
20. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
21. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/relateditems.cfm?page_title=medical%20device%20recalls&item1_text=medical%20device%20recalls%20&item1_url=www.fda.gov/medicaldevices/safety/recallscorrectionsremovals/listofrecalls/default.htm&item2_text=fda%20enforcement%20report%20index&item2_url=www.fda.gov/safety/recalls/enforcementreports/default.htm

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