REPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
LE DIRECTEUR GÉNÉRAL

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٧/٢٥
رقم الصادر: ٤٣/١٨٣/٧/١٢
بيروت، في: ١٧ تشرين الثاني ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي Verify Bowie - Dick Test Card.

الجهاز المعني بالمتابعة:

- Verify Bowie - Dick Test Card
  Trade Mark: Steris Corporation
  Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

الذي يفيد بوجود خلل أثناء استعمال الصنف المذكور أعلاه والذي يؤدي الى خلل في عملية مراقبة أجهزة التعقيم، نرجو منكم تعميم هذه النشرة على المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA.

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

المدير العام
وليد عمار

وثيقة مطابقة للأصل
بيروت في ١٧ تشرين الثاني ٢٠١٢
رئيس قسم الدروس والقضايا
العلاقات الصحية والدولية
عبد ضومط

U.S. Food & Drug Administration

Enforcement Report - Week of September 26, 20[illegible]

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Product Detail

Product Description	Verify® Bowie-Dick Test Card, Model #S3098, Steris Biological Operations, 9325 Pinecone Drive, Mentor, OH 44060 The Verify Bowie-Dick Test Card consists of a card printed on one side with bars of chemical indicator ink. On the opposite side of the card, space is provided for critical cycle information to be recorded. The card is laminated inside a thin clear plastic enclosure. The enclosure has two holes in it to allow air removal and steam penetration. The preassembled test is used to evaluate the effectiveness of air removal from the sterilizer chamber during prevacuum pulse steam sterilizer cycle. Following a prevacuum cycle, the chemical bars of the Bowie-Dick Test card uniformly darken indicating that residual air has been sufficiently removed to allow complete steam penetration into the test card. If air is trapped in the card during the exposure phase of the cycle, the color change of the bars will be incomplete or uneven. Thus the card can provide an immediate indication of inadequate removal of air during a cycle. The Bowie-Dick Type test is performed in an empty chamber each day the sterilizer is to be used, usually before the first sterilization cycle.
Recall Number	Z-2417-2012
Classification	Class II
Code Info	Model #S3098, Serial #'s: H20013, H20014, and H20016.
Product Distributed Qty	629 cards
Reason For Recall	STERIS has learned that the Verify Bowie Dick Test Card are not performing to product specifications. Specifically, test cards have resulted in false fail results when sterilizer performance is within acceptable ranges.

Event Detail

Event Id	63129
Product Type	Devices
Status	Ongoing
Recalling Firm	Steris Corporation
City	Mentor
State	OH
Country	US
Voluntary / Mandated	Voluntary: Firm Initiated
Recall Initiation Date	2012-07-03
Initial Firm Notification of Consignee or Public	Letter
Distribution Pattern	Worldwide Distribution--USA (nationwide) including the states of AL, CA, CO, CT, FL, GA, IA, IN, IL, KS, KY, LA, MA, MD, MI, MN, MO, MS, NC, NE, NJ, NM, NY, OH, OK,OR, PA, RI, SC, TX, UT, VA, WA, WI, WV and WY. and the country of Canada.

U.S. Food and Drug Administration
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