REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧١٢٥
رقم الصادر : ١٢/١/٢٨٦٢١
بيروت، في : ٣٠ آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Cardioverter Defibrillator

الجهاز المعني بالمتابعة:

- Cardioverter Defibrillator
- Trade Mark: Boston Scientific Cardiac Rhythm Management Group
- Local Representative: Medilife s.a.l

بناء على التقرير الصادر عن وكالة ال FDA ،
الذي يشير الى وجود خلل في عمل الجهاز المذكور أعلاه، 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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Medical & Radiation Emitting Device Recalls

Class 2 Recall
ENERGEN DR ICD

See Related Information[21]

Date Posted	August 16, 2013
Recall Number	Z-1979-2013
Product	Boston Scientific, ENERGEN DR ICD, Model E143. The device is an Implantable Cardioverter Defibrillator.
Code Information	Serial # 108063
Recalling Firm/ Manufacturer	Boston Scientific CRM Corp 4100 Hamline Ave N Saint Paul, Minnesota 55112-5700
Consumer Instructions	Contact the recalling firm for information
Reason for Recall	Boston Scientific CRM manufacturing quality system recently discovered test artifacts (related to shock charge time) in a small number of implantable defibrillators (ENERGEN DR ICD model E143) which require further investigation. While these devices successfully passed all manufacturing tests and met all requirements, they showed a slightly longer charge time than other devices during a manufactu
Action	Consignee was sent on 7/15/13 a Boston Scientific "Medical Device Retrieval" letter dated July 12. 2013. The letter described the product problem and informed the consignee that they will replace the product removed from their inventory. For further questions, contact Boston Scientific Technical Services at 1 800 227-3422.
Quantity in Commerce	1 (4 devices were implanted and are not part of this action)
Distribution	US distribution in the state of Tennessee.

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Page Last Updated: 08/26/2013

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