



Medical Device Control Office - Press release - Windows Internet Explorer

http://www.mdco.gov.hk/english/press/press.html

Department of Health
The Government of the Hong Kong Special Administrative Region

GOVHK 香港政府一站通 TEXT ONLY 繁體版 简体版

SEARCH [] SITE MAP []

Medical Device Control Office

Press Release

Press Release

- Advisory Notice on Use of Heartbeat Regulating Products (Posted on 13 April 2007)
- DH Closely Monitoring Safety of Lifescan Blood Glucose Meter (19 December 2006)
- DH and Customs Keep Close Watch on Recall of Contact Lens Solutions (23 November 2006)
- DH Monitoring Recall of Four AMO Contact Lens Solutions (22 November 2006)
- Software Problem Found in Programming Devices for Implantable Pacemakers (19 October 2006)
- Voluntary Recall of Heartbeat Regulating Products (27 June 2006)
- DH notified of intra-uterine contraceptive device cases (18 January 2006)
- Update on Removal of Contraceptive Device (24 December 2005)
- Removal of Contraceptive Device (13 December 2005)
- Follow-up Action on Medtronic Sigma® Pacemakers (1 December 2005)

網際網路 100%





Adverse Incident Reporting System



Medical Device Control Office - Report adverse incidents - Microsoft Internet Explorer

檔案(E) 編輯(E) 檢視(V) 我的最愛(A) 工具(T) 說明(H)

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Merriam-Webster M-W Online Dictionary M-W Online Thesaurus Word of the Day

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Medical Device Control Office



Report Adverse Incidents

Report Adverse Incidents

- Report Medical Device Adverse Incidents**

The objective of this Medical Device Adverse Incident Reporting System is to improve the protection of health and safety of patients, users and others through information dissemination that may reduce the likelihood of, or prevent, repetition of adverse incidents, or alleviate consequences of such repetition.

This System is designed for the Local Responsible Persons to submit the reportable adverse incidents related to their listed products, and which are suspected to have caused death or serious injury, or which may lead to death or serious injury if it recurs. *The act of reporting an incident is not to be construed as an admission of manufacturer,*

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Medical Device Control Office - On-line reporting - Microsoft Internet Explo...


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網址(D) http://search.mdco.gov.hk/english/report/report_rf/report_rf_login.php 移至 連結

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The Government of the Hong Kong Special Administrative Region

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Medical Device Control Office

Report Adverse Incidents



Report Adverse Incidents > Reporting Form


- Reporting form

Please Login (For Local Responsible Persons Only)

User Name

Password

For others, please use the User Reporting Form   to report adverse incidents involving medical devices to the Medical Device Control Office.

 Adobe Reader is required for viewing and printing the





http://search.mdco.gov.hk/english/report/report_rf/User_Reporting_Form.pdf -...

檔案(E) 編輯(E) 檢視(V) 我的最愛(A) 工具(T) 說明(H)

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96%

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MEDICAL DEVICE CONTROL OFFICE

USER REPORTING FORM – MEDICAL DEVICE INCIDENTS

This is a voluntary report form for reporting suspected problem with a medical device that **may present a hazard**. Submission of this report does not constitute an admission by the reporter of liability for the event and its consequences. It is also not a conclusion that the device caused or contributed to the adverse event. Information of individual reporter and patient will be treated in strict confidence. For enquiries, please contact the MDCO at telephone no. 2961 8788.

MDCO Report No.
(Official Use Only)

I. DEVICE INFORMATION

1. Device Description			
2. Brand Name and Model			
3. Serial No., Batch No., or Lot No.		4. MDCO Listing No. (if known)	
5. Is the device or its packaging available for inspection? <input type="checkbox"/> Yes <input type="checkbox"/> No			

II. SUPPLIER INFORMATION

1. Company Name			
2. Name of Contact Person		3. Telephone No.	

8.26 x 11.69 英寸

1 / 1

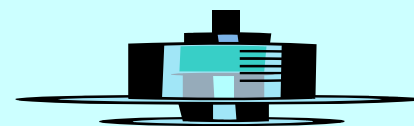
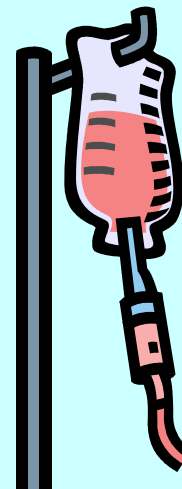
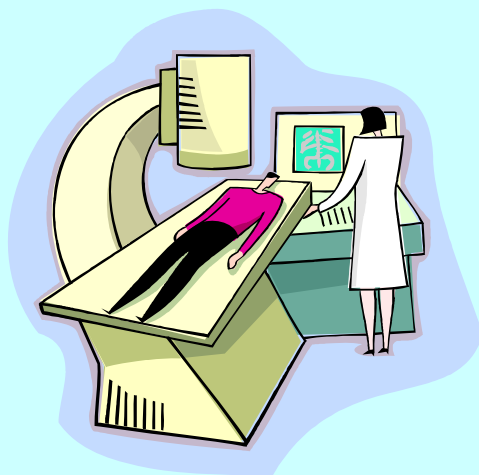
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Adverse Incidents (2 Aug 2005~23 Apr 2007)

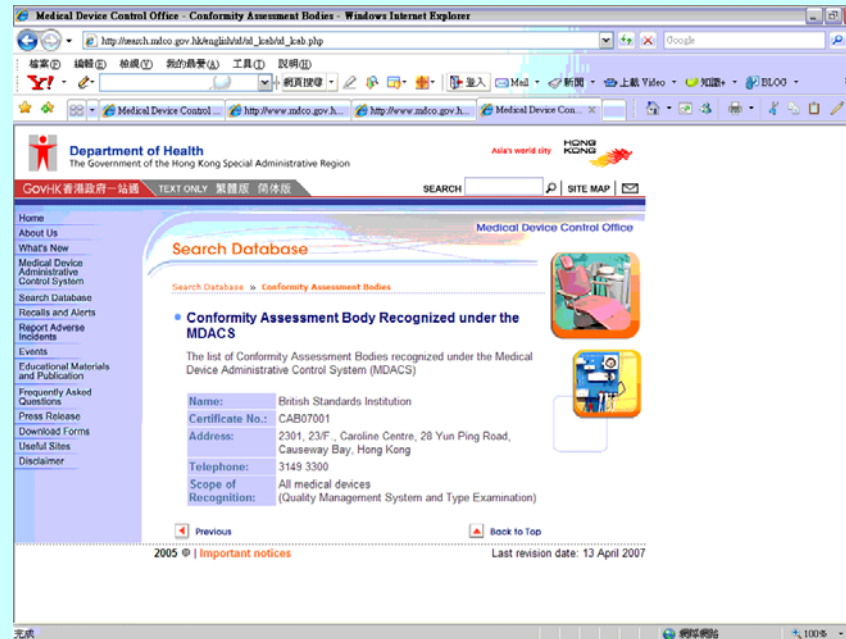


- ◆ Cases reported 14
- ◆ Cases completed : 6





- ◆ CAB is a body recognized by the MDCO to engage in the performance of procedures for determining whether the relevant MDACS requirements are fulfilled.

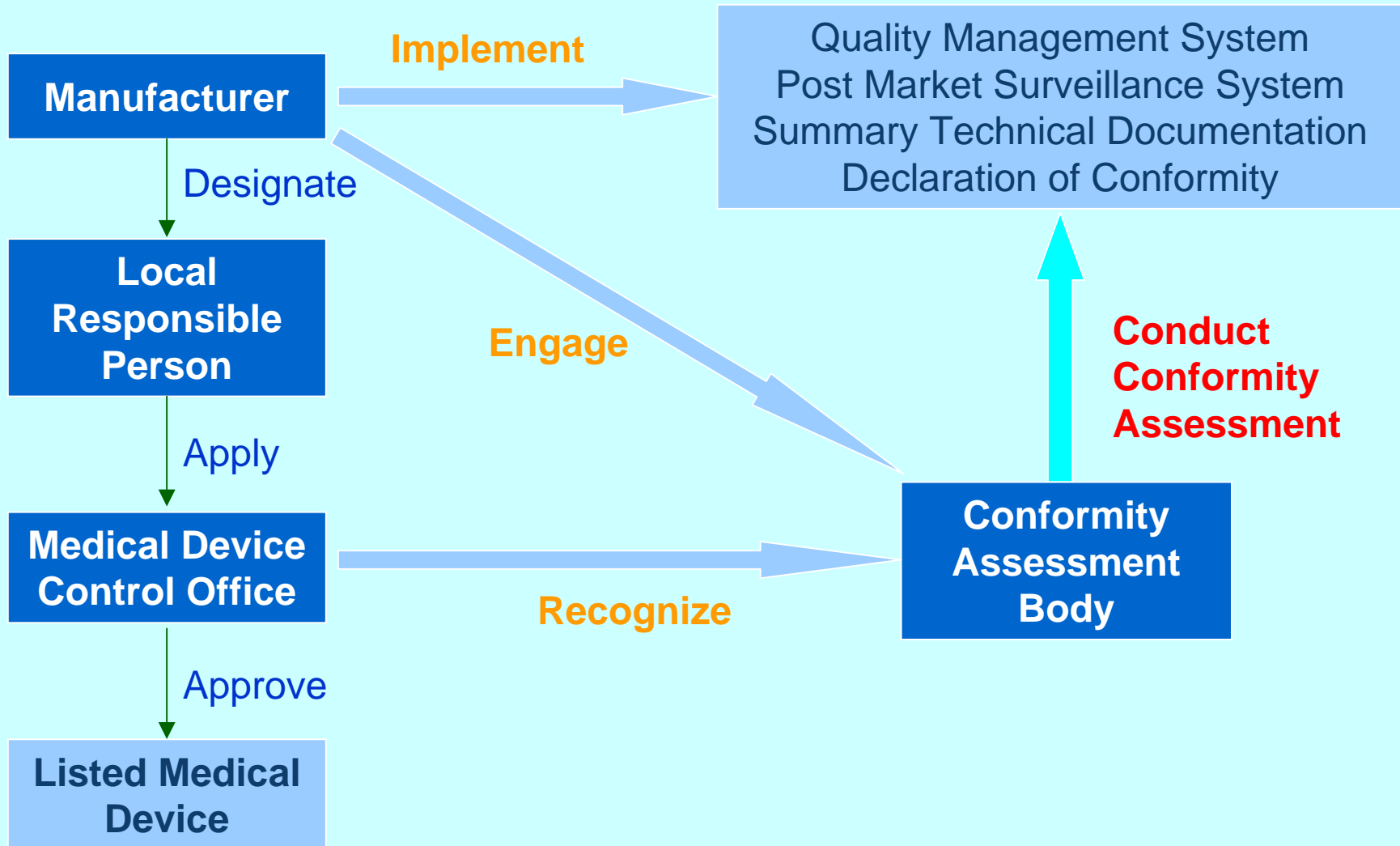


The screenshot shows a web browser window displaying the Medical Device Control Office website. The page is titled "Search Database" and lists "Conformity Assessment Bodies". A search result is shown for a body recognized under the MDACS. The details are as follows:

Name:	British Standards Institution
Certificate No.:	CAB07001
Address:	2301, 23/F, Caroline Centre, 28 Yun Ping Road, Causeway Bay, Hong Kong
Telephone:	3149 3300
Scope of Recognition:	All medical devices (Quality Management System and Type Examination)

At the bottom of the page, there is a "2005 | Important notices" section and a "Last revision date: 13 April 2007" note.







Alternate Route of Conformity Assessment



- ◆ Marketing approval from GHTF founding members
 - Australia
 - Canada
 - European Union (countries have implemented European Council Directives)
 - Japan
 - USA





- ◆ A local manufacturer is a manufacturer whose business as a manufacturer of medical devices has either been registered in Hong Kong pursuant to the Business Registration Ordinance (Cap. 310) or is part of a business which has been so registered.
- ◆ QMS requirements: ISO 13485
- ◆ Commencement: Mar 2007





- ◆ An importer is a legal or natural person who brings or entrusts others to bring medical devices that fall within the scope of the MDACS into Hong Kong.
- ◆ Proposed document: GN-07
- ◆ Comments: before 30 Apr 2007





MDCO Website



Medical Device Control Office - Windows Internet Explorer

http://www.mdco.gov.hk/index.html

Department of Health
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Medical Device Control Office

What's New

- Conformity Assessment Body Recognized under the MDACS (Posted on 13 April 2007) >> more

Events

- Workshops on Application for Listing Medical Devices (Updated on 12 April 2007) >> more

Press Release

- Advisory Notice on Use of Heartbeat Regulating Products (Posted on 13 April 2007) >> more

Recalls and Alerts

- Summary of Medical Device Safety Information (16 March 2007) >> more

Best viewed with Internet Explorer 5.0 / Netscape 4.7 or above and with 800 x 600 resolution

GovHK

預防禽流感 PREVENT AVIAN FLU

2006-07 Policy Address

2007-08

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- ◆ Workshops: 23
- ◆ Educational Seminars: 6





**醫療儀器種類多
安全效能認清楚
小心選用免出錯
保障健康最穩妥**

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衛生署
Department of Health

醫療器械管制處
Medical Device Control Office
電話 Tel: 2961 8788
傳真 Fax: 3157 1286
電郵 Email: mdco@dh.gov.hk

<http://www.mdco.gov.hk>



**選購和使用
醫療儀器
應注意什麼**

輪椅 助聽器 血壓計 持續性正壓呼吸機
血糖計 電動輪椅 輪椅壓力 氧濃縮器 體溫計 助聽器 助行器 電動輪椅 助聽器 持續性正壓呼吸機



**? 甚麼是 ?
「醫療儀器」**





- ◆ Full scope of MDACS:
 - Mid 2007
- ◆ Regulatory Impact Assessment:
 - May ~ Nov 2007
 - Includes public consultation
- ◆ Report to Legislative Council: end 2007





Thank You!

