



Medical Device Administrative Control System (MDACS)

**Department of Health
The Government of the Hong Kong Special Administrative Region
of the People's Republic of China**





- ◆ Background
- ◆ Rationale
- ◆ Scope
- ◆ Systems and Implementation Progress
- ◆ MDCO Website
- ◆ Publicity Programmes
- ◆ Way Forward





- ◆ No specific control or monitoring of medical devices before 2003
- ◆ Consultation Document on Regulation of Medical Devices issued in July 2003
- ◆ Discussion in LegCo Panel on Health Services in March 2004
 - Implementation of an administrative control system by phases (MDACS)





- ◆ On voluntary basis
- ◆ In line with the ***Global Harmonization Task Force (GHTF)*** Recommendations
(<http://www.ghtf.org>)
- ◆ Tailored to suit the local situation
- ◆ No unnecessary burden to the trade and the government





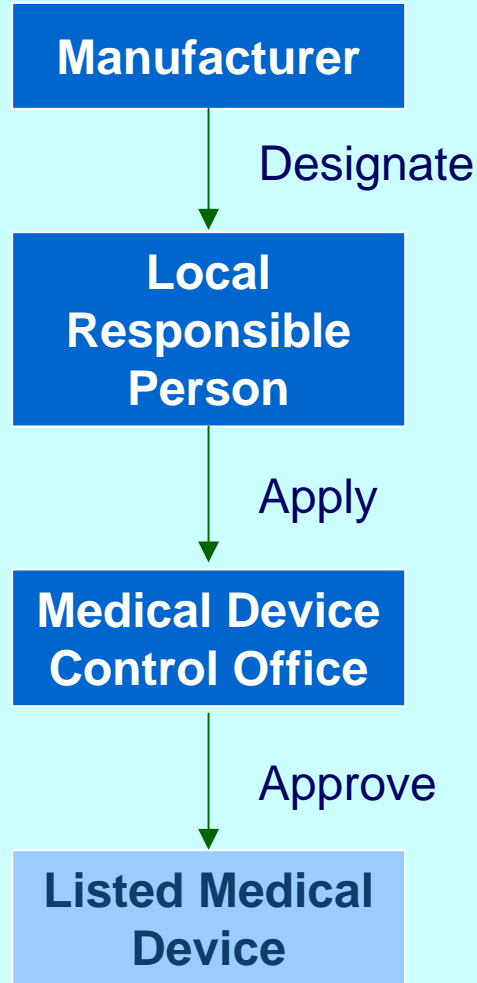
- ◆ Listing of Classes II, III and IV medical devices
- ◆ Medical Device Safety Alert System
- ◆ Adverse Incident Reporting System
- ◆ MDCO Webpage (www.mdco.gov.hk)
- ◆ Recognition of Conformity Assessment Bodies
- ◆ Listing of Local Manufacturers
- ◆ Listing of Importers (*consultation in progress*)







Medical Device Listing Process





◆ Information on the certificate

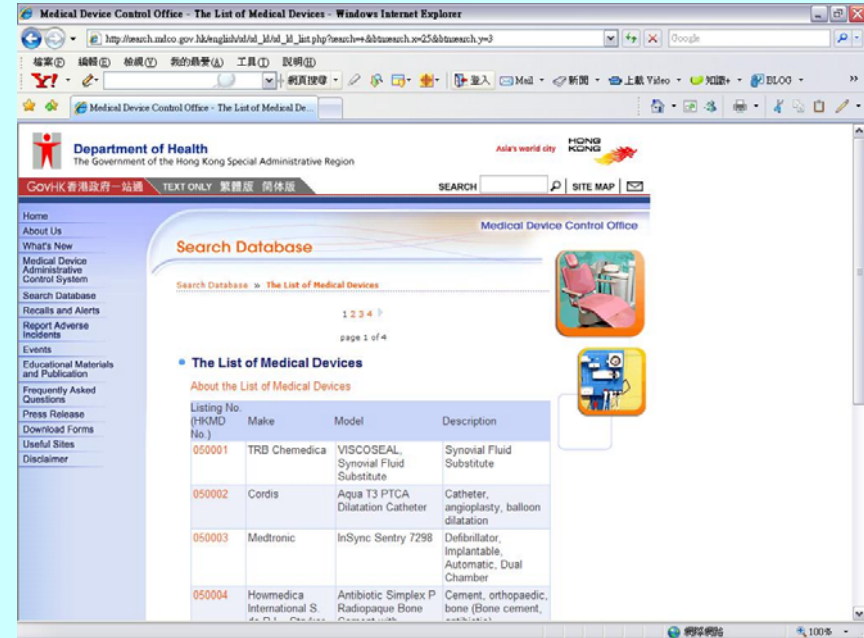
- Listing no.
- Make and model
- Device description
- Manufacturer and address
- Manufacturing sites
- Local Responsible Person
- Date of issue
- Date of expiry

香港特別行政區政府 衛生署 醫療儀器管制辦公室 網站: www.mdco.gov.hk		Medical Device Control Office, Department of Health, Government of the Hong Kong Special Administrative Region Website: www.mdco.gov.hk
表列證書 CERTIFICATE OF LISTING		
表列號碼 Listing No.	:	050000
廠名及型號 Make and Model	:	ABC Model D
儀器名稱 Device Description	:	Pacemaker, cardiac, implantable
製造商 Manufacturer	:	ABC D-12345 Main-München, Germany
製造地點 Manufacturing Site	:	ABC D-12345 Main-München, Germany
本地負責人 Local Responsible Person	:	ABC Hong Kong Ltd
<p>茲證明上述產品已在衛生署的「醫療儀器行政管理制」中表列。上述本地負責人已由製造商委任，並承諾遵守「醫療儀器行政管理制」的規定。</p> <p>This is to certify that the product described above has been listed with the Department of Health under the Medical Device Administrative Control System (MDACS). The above Local Responsible Person has been designated by the Manufacturer and has undertaken to comply with the MDACS requirements.</p>		
發出日期 Date of issue	:	1 Jan 2005
有效至 Valid until	:	31 Dec 2009
衛生署署長 (何家慧醫生代行) (Dr Rita HO) for Director of Health		





- ◆ Commencement
 - Class IV: Nov 2004
 - Classes II/III: Nov 2005
- ◆ Applications received: 222 (until 23 Apr 2007)
- ◆ Applications approved: 47 (until 23 Apr 2007)



The screenshot shows the Medical Device Control Office website. The main content area displays a table titled "The List of Medical Devices" with the following data:

Listing No. (HKMD No.)	Make	Model	Description
050001	TRB Chemeca	VISCOSEAL, Synovial Fluid Substitute	Synovial Fluid Substitute
050002	Cordis	Aqua T3 PTCA Dilatation Catheter	Catheter, angioplasty, balloon dilatation
050003	Medtronic	InSync Sentry 7298	Defibrillator, Implantable, Automatic, Dual Chamber
050004	Howmedica International S.	Antibiotic Simplex P Radiopaque Bone Cement	Cement, orthopaedic, bone (Bone cement, antibiotic)





◆ Sources of safety information

- GHTF National Competent Authority Report Exchange Program (NCAR Program)
- Overseas authorities (e.g. FDA, MHRA & Health Canada)
- Local Responsible Persons
- Device suppliers and manufacturers
- Hospitals and healthcare institutions
- News media...





◆ Classes of safety alerts

- Class 1: reasonable chance will cause serious health problems or death
 - Urgent safety alert
- Class 2: possibility will cause temporary or reversible health problem
 - Monthly summary
- Class 3: little chance will cause health problems
 - No action





- ◆ Alerts screened 907
- ◆ Affected devices sold in HK 154
 - Class 1: 54 cases
 - Class 2: 100 cases



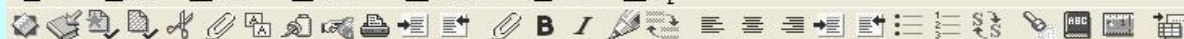


Urgent Safety Alert Emails



New Memo - Lotus Notes

File Edit View Create Actions Text Help



Workspace WK LAU - Inbox WK LAU (Archive) - Inbox Voluntary Field Action regarding Guidant Contak R... New Memo x notes

Send Send and File Save As Draft Address... Delivery Options... Tools

WK LAU

10/04/2006 18:41

To:

cc:

bcc:

Subject: Voluntary Field Action regarding xxxxxx Implantable Cardiac Defibrillators

Urgent Return Receipt

Our file ref. no.: (2) in S/F(150) in DH/MDCO/20-5/2

Dear Sir/Madam,

Please be informed that YYYYYY Corporation has issued a press release on their corporate website regarding a voluntary field action on the captioned devices. Details could be found at the website address http://www.yyyyyyy.com/news/600/web_release/nr_000624.shtml .

If you are in possession of any affected units, please contact your supplier for remedial actions.

Yours faithfully,
Alfred K.F. NGAI
for Director of Health

Medical Device Control Office, Department of Health
The Government of the Hong Kong Special Administrative Region
18/F, Wu Chung House.

Body of message

Default Sans Ser^ 10 ^ [None]

Office





Medical Device Control Office - Recalls and alerts - Windows Internet Explorer

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

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

GOVHK 香港政府一站通

Medical Device Control Office

Recalls and Alerts

Recalls and Alerts

The following document is a summary of some medical device safety information related to potentially hazardous cases. It only serves as a quick reference and in no way should be considered as exhaustive and up-to-date. Please refer to the source of information and your product supplier for details. (Updated on 16 March 2007).

- [Boston Scientific Vitality and Assure Implantable Cardioverter Defibrillator \(ICD\) Families and Contak Renewal Cardiac Resynchronisation Therapy Defibrillator \(CRT-D\) Families \(15 March 2007\)](#)
- [Medtronic Model 3770GK GATEKEEPER Reflux Repair Systems \(6 March 2007\)](#)
- [Waverleyglen Portable Reachers 24" and 36" \(5 March 2007\)](#)
- [Various Models of HoMedics Heating Pads \(9 February 2007\)](#)
- [Biomerieux Vironostika HIV-1 Microelisa Systems \(7 February 2007\)](#)
- [Physio-Control Products \(25 January 2007\)](#)
- [Select lots of CIBA Vision O₂Optix \(Iotrafilcon B\) Soft Contact Lenses \(16 January 2007\)](#)





http://www.mdco.gov.hk/english/recalls/files/alerts_20070316.xls - Windows Internet Explorer

http://www.mdco.gov.hk/english/recalls/files/alerts_20070316.xls

Medical Device Control Office

Waverleyglen Systems Ltd - Portable Reacher 24" and 36"

Major Safety Alerts in March 2007 (This page is subject to further review)

The following safety alerts has a reasonable chance that the product will cause serious health problems or death. These cases will be forming part of the summary of March 2007 and more details will be provided when available

*Note: FDA = Food and Drugs Administration, United States of America; MHRA = Medicines and Healthcare products Regulatory Agency, United Kingdom; Health Canada = Health Canada

MDCO Ref. No.	Description of Product	Source of Information ¹	Reference No. by Source	Alert Type by Source	Date of Issue (YYYY/MM/DD)	Location
	Waverleyglen Systems Ltd - Portable Reacher 24" and 36"	Health Canada	34150	Type I	2007/03/05	
	Medtronic Model 3770GK GATEKEEPER Reflux Repair System	MHRA	2007/002/014/081/006	Field Safety Corrective Action	2007/03/06	Medtronic
	Boston Scientific Vitality and Assure Implantable Cardioverter Defibrillator (ICD) Families and Contak Renewal Cardiac Resynchronisation Therapy Defibrillator (CRT-D) Families	MHRA	MDA/2007/023	Medical Device Alert	2007/03/15	Boston Scientific

Major Safety Alerts in Mar 2007 / February 2007 / January 2007 / December 2006 / November

不明的區域

