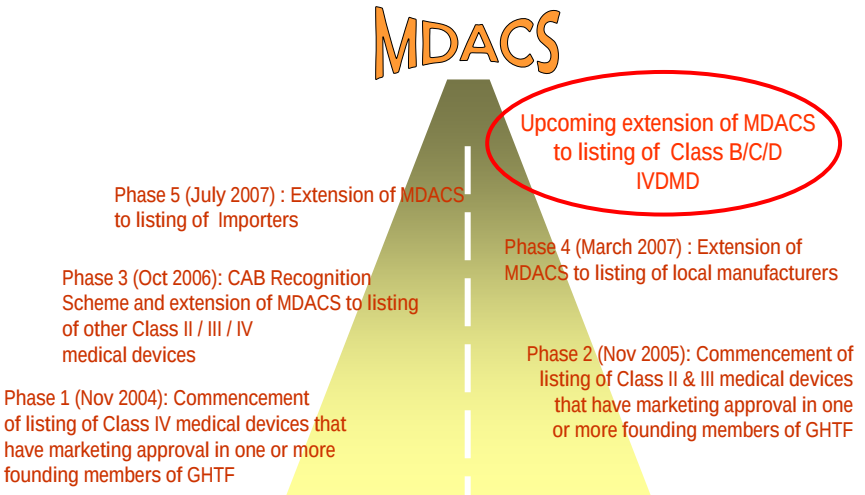
Proposed Requirements for the Listing Class B/C/D In Vitro Diagnostic (IVD) Medical Devices

Medical Device Control Office
Department of Health
16 March 2009

Towards a Complete Medical Device Administrative Control System (MDACS)



What're the In Vitro Diagnostic (IVD) Medical Devices?

- Definition
  - A category of Medical Devices
  - In-Vitro examination of specimens derived from human body
  - Purposes: Diagnostic, Monitoring or Compatibility
- Includes
  - Reagents
  - Calibrators
  - Control materials
  - Specimen receptacles, software & related …

Listing In Vitro Diagnostic (IVD) Medical Devices

- Rationale
  - On Voluntary Basis
  - Devices are safe and effective
  - In line with the recommendations of Global Harmonization Task Force (GHTF)
  - Classify and control according to risk levels of IVDMD
  - Pre-market control and post-market control

Listing In Vitro Diagnostic (IVD) Medical Devices

PROPOSED DOCUMENTS	
Guidance Notes: GN-06 (Proposed)	Guidance Notes for Listing Class B/C/D In Vitro Diagnostic (IVD) Medical Devices
Technical Reference: TR-006 (Proposed)	Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

Listing In Vitro Diagnostic (IVD) Medical Devices

RELATED DOCUMENTS	
Guidance Notes: GN–01 (2005 version)	Overview of the Medical Device Administrative Control System
Guidance Notes: GN-03 (2007 version)	Guidance Notes for Adverse Incident Reporting by Local Responsible Persons
Code of Practices: COP-03 (2007 version)	Code of Practice for Local Responsible Persons
Technical Reference: TR-002 (2006 version)	Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)

Classification System for IVD Medical Devices

In line with GHTF Document: SG1/N046:2008 Principles of Medical Devices Classification

CLASS	RISK LEVEL	EXAMPLES
A	Low Individual Risk and Low Public Health Risk	Clinical Chemistry Analyser Prepared selective culture media
B	Moderate Individual Risk and/or Low Public Health Risk	Vitamin B12 Pregnancy self testing Anti-Nuclear Antibody Urine Test strips
C	High Individual Risk and/or Moderate Public Health Risk	Blood glucose self testing HLA typing PSA screening Rubella
D	High Individual Risk and High Public Health Risk	HIV Blood donor screening HIV Blood diagnostic

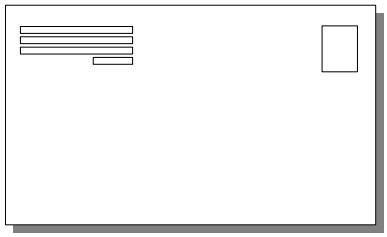
Examples of IVD Medical Devices Classification

DEVICES	IVDMD CLASS	CLASSIFICATION RULE
Test to detect infection by Hepatitis B (HBV)	D	Rule 1
Test to determine Human Leukocyte Antigen (HLA)	C	Rule 2
Testing of Huntington's Disease	C	Rule 3
Blood Glucose Monitoring	C	Rule 4
Urine Test-strips	B	Rule 4
Plain urine cup (an example of specimen receptacle)	A	Rule 5
H.Pylori markers	B	Rule 6
Controls that the qualitative and quantitative value assigned by the user and not the manufacturer	B	Rule 7

Persons Eligible to Apply for the Inclusion of an IVDMD into the List of Medical Device

Only Person(s) designated by the manufacturer.

Designation Letter



(Please see Sections 3, 4 and 5 of the Guidance Notes GN-01 for the requirements and obligations of an LRP.)

Local Responsible Person

- **LRP's Obligations**
  - Making applications for listing the medical devices under the MDACS
  - Communication with users, importers, the public and the Government
  - Maintaining list of importers and distribution records
  - Handling complaints
  - Provision of maintenance and services
  - Tracking of specific medical devices…

(Please see Sections 3, 4 and 5 of the Guidance Notes GN-01 for the requirements and obligations of an LRP.)

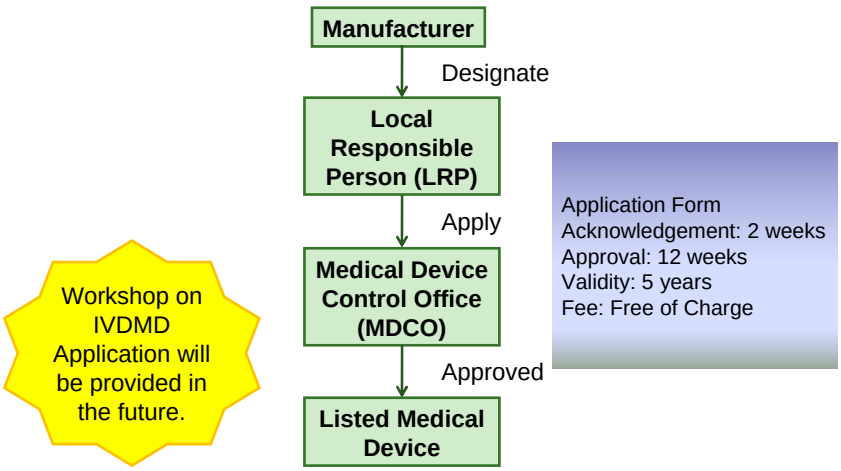
Local Responsible Person

- Management of alerts, modifications and recalls
- Management of reportable adverse incidents* in Hong Kong
- General requirements
  - reporting changes
  - provisions of records
  - advertisement requirements
  - indemnifying the Government…

**Please refer to the Guidance Notes: GN-03 for details*

(Please see Sections 3, 4 and 5 of the Guidance Notes GN-01 for the requirements and obligations of an LRP.)

Application Procedures



If you have comments, …

Your comments on the proposed requirements and the proposed Guidance Notes he GN-06 and Technical Reference TR-006 are most welcome. But let us have your comments **not later than 30 April 2009**, please.

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THANK YOU

Q&A