Medical Device Administrative Control System

Briefing session on Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Device

Department of Health

Medical Device Control Office

Briefing Agenda

- Medical Device Control Office (MDCO)
- Medical Device Administrative Control System (MDACS)
- Definition and Classification of IVD Medical Devices
- Key points on Changes of Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Device
- Q&A

Medical Device Control Office

Background

- **The Medical Device Control Office (MDCO) was established in July 2004.**
- **The MDCO is responsible for**
  - implementing the Medical Device Administrative Control System (MDACS)
  - developing a long-term statutory regulatory framework for medical devices.

Background

- **Existing control**
  - No **specific** legislation to regulate the importation or sale of medical devices in HK.
  - But some medical devices may be regulated by existing pieces of legislation such as the Pharmacy and Poisons Ordinance, Radiation Ordinance, etc.
- **Jul 2003**
  - Consultation Document entitled “Regulation of Medical Devices
- **Nov 2004**
  - Medical Device Administrative Control System (MDACS) launched

Medical Device Administrative Control System (MDACS)

Medical Device Administrative Control System

- **Voluntary** system
- To be eventually superseded by future regulation
- Goal of the MDACS
  - To raise the public's awareness of the use of safe medical devices
  - To enable traders to familiarize themselves with the future mandatory requirements
  - To provide an opportunity to collect more information and feedback from the industry as a reference to fine tune the long-term regulatory framework

Scope of the MDACS

- Listing System
  - Medical Devices (Class II – IV)
  - In Vitro Diagnostic (IVD) Medical Devices (Class D)
  - Local Manufacturers
  - Importers
  - Distributors
- Recognition of Conformity Assessment Bodies (CAB)
- Recall and Adverse Incident Reporting System
  - If a reportable recall or incident concerning a listed device happens in Hong Kong, it must be reported by the LRP to Medical Device Control Office (MDCO). (Guidance Notes GN-03)

Implementation Progress

- Phase I (Nov 2004): Listing of Class IV devices
- Phase II (Nov 2005): Listing of Class II & III devices
- Phase III (Oct 2006): CAB Recognition Scheme
- Phase IV (Mar 2007): Listing of local manufacturers
- Phase V (Jul 2007): Listing of importers
- Phase VI (Dec 2009): Listing of Class D IVDMD
- Phase VII (Apr 2015): Listing of Distributors
- Phase VIII (early 2019): Listing of Class B & C IVDMD

Information from MDCO website (www.mdco.gov.hk)

- Related Guidance Notes, Code of Practice and Technical References
  http://www.mdco.gov.hk/english/mdacs/mdacs_gn/mdacs_gn.html
- Application Forms
  http://www.mdco.gov.hk/english/mdacs/mdacs_af/mdacs_af.html
- The List of Medical Devices
  http://search.mdco.gov.hk/english/sd/sd_ld/sd_ld.php

Medical Device Control Office - Issued Documents - Windows Internet Explorer

http://www.mdco.gov.hk/english/mdacs/mdacs_gn/mdacs_gn.html

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Medical Device Control Office

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issued Documents

Administrative Control System » Issued Documents

ce Notes for the Medical Device Administrative System

documents for the Medical Device Administrative Control System le in pdf format:

- [GN-00] Guidance Notes for Definitions and Abbreviations for Medical Device Administrative System
- [GN-01] Overview of the Medical Device Administrative Control System (Note: The "Classification Rules for Medical Devices" given in Appendix 1 of this guidance document may be updated from time to time. You may wish to refer to the most updated version included in the Technical Reference [TR-003] Classification Rules for Medical Devices published by Department of Health.)
- [GN-01S] Supplementary Notes for Submitting Applications for Listing Medical Devices under the Medical Device Administrative Control System
- [GN-02] Guidance Notes for Listing Class I, II & III Medical Devices (Jul 2011 Edition) NEW!

http://www.mdco.gov.hk/english/mdacs/mdacs_gn/mdacs_gn.html 網際網路 150%

Issued Documents

Guidance Notes	Reference Document
Guidance Notes for Definitions and Abbreviations for Medical Device Administrative System	GN-00
Overview of the Medical Device Administrative Control System	GN-01
Guidance Notes for Listing Class II/III/IV Medical Devices	GN-02
Guidance Notes for Adverse Incident Reporting by Local Responsible Persons	GN-03
Conformity Assessment Framework and Conformity Assessment Bodies	GN-04
Guidance Notes for Listing In Vitro Diagnostic (IVD) Medical Devices	GN-06
Guidance Notes for Listing of Importers of Medical Devices	GN-07
Guidance Notes for Listing of Local Manufacturers	GN-08
Guidance Notes for Listing of Distributors	GN-09

Issued Documents

Technical Reference	Reference Document
Principles of Conformity Assessment for Medical Devices	TR-001
Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)	TR-002
Classification Rules for Medical Devices	TR-003
Essential Principles of Safety and Performance of Medical Devices	TR-004
Additional Medical Device Labelling Requirements	TR-005
Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	TR-006

Code of Practice	Reference Document
Cope of Practice for Local Responsible Persons	COP-01
Cope of Practice for Conformity Assessment Bodies	COP-02
Cope of Practice for Listed Local Manufacturers	COP-03
Cope of Practice for Listed Importers of Medical Devices	COP-04

In Vitro Diagnostic Medical Devices (IVDMD)

Definition of IVDMD

- A device, whether used alone or in combination, intended by the manufacturer for in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes
- This is includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

Classification of IVDMD

- Technical Reference TR-006: Principles of IVDMD Classification
  - Rule 1 to Rule 7
- Risk-based approach – the degree of risk classified for medical devices according to the recommended classification scheme of the Global Harmonization Task Force (GHTF)
  - Class A being the category of the lowest risk and Class D the highest.
- The device should be allocated to the highest class indicated when more than one of the classification rules apply to the device

Classification of IVDMD

Class	Individual Risk	Public Health Risk	Example
D	High	High	HIV infection test; ABO grouping
C	High	Moderate	Blood glucose monitoring, HIV viral load
B	Moderate	Low	Pregnancy self testing
A	Low	Low	Specimen receptacle

Key points on Changes of Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Device

Draft Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Device

- Our Office is planning to extend the listing scope of In Vitro Diagnostic Medical Device (IVDMD) to cover Class B and C.
- The Draft Guidance Notes is now posted on MDCO website for comments：
  - Draft Guidance Notes for Listing Class B, C and D In Vitro Diagnostic (IVD) Medical Devices (GN-06)
  - Draft Application Form for the Listing of In Vitro Diagnostic Medical Devices (MD-IVD)
  - Draft Essential Principles Conformity Checklist For In Vitro Diagnostic Medical Devices (MDIVD_CCL)

Draft Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Device

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W3C WAI-AA WCAG 2.0
W3C HTML 4.01

Medical Device Control Office

What's New

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• Briefing sessions on Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Device

Our Office is planning to extend the listing scope of In Vitro Diagnostic Medical Device to cover Class B and C. Two briefing sessions with the same content but in different languages will be held. Details of the briefings are as follows:

Briefing Session No.1 (conducted in Cantonese) :
Date : 4 Dec 2018
Time : 2:30 p.m. to 3:30 p.m.
Venue: Lecture Theatre, Public Health Laboratory Centre, 382 Nam Cheong Street, Kowloon

Briefing Session No.2 (conducted in English) :
Date : 4 Dec 2018
Time : 4:00 p.m. to 5:00 p.m.
Venue: Lecture Theatre, Public Health Laboratory Centre, 382 Nam Cheong Street, Kowloon

Enrolment is free. To enroll, please download and complete the enrolment form and fax the completed form to the Medical Device Control Office at (852) 3157 1286 on or before 26 Nov 2018.

The Guidance Notes is now posted for comments.

- Draft Guidance Notes for Listing Class B, C and D In Vitro Diagnostic (IVD) Medical Devices
- Draft Application for the Listing of In Vitro Diagnostic Medical Devices (IVDMD)
- Draft Essential Principles Conformity Checklist For IVD medical devices

Draft Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Device

- Draft Guidance Notes for Listing Class B, C and D In Vitro Diagnostic (IVD) Medical Devices (GN-06)
  - Updated to 2018 version, no significant changes
- Draft Application Form for the Listing of In Vitro Diagnostic Medical Devices (MD-IVD)
  - Updated to 2018 version, no significant changes
- Draft Essential Principles Conformity Checklist For In Vitro Diagnostic Medical Devices (MDIVD_CCL)
  - New Checklist (2018 version)

Draft Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Device

- GN-06 Revision summary

Edition Number	Date of Revision	Summary of Revisions	Reference Number
2.0	31 Oct 2018	• Clause 1 (Introduction: scope) has been updated; • Clause 5.3 (Submission of applications (softcopies)) has been updated; • Clause 7 (Enquiries) has been updated; • Application Form for Listing has been updated to MD-IVD (2018 Edition); and • Appendix II Sample Essential Principles Conformity Checklist has been updated to MDIVD-CCL (2018 Edition)	GN-06:2018(E)

Draft Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Device

- New “Essential Principles Conformity Checklist For In Vitro Diagnostic Medical Devices”(MDIVD-CCL) replaced the “Essential Principles Conformity Checklist”(MD-CCL)
- Where GHTF founding members approvals have been obtained on or before 31 December 2004, the Essential Principles Conformity Checklist For In Vitro Diagnostic Medical Devices (MDIVD-CCL) shall be submitted only upon request.

Medical Device Control Office
Department of Health

Medical Device Administrative Control System
Essential Principles Conformity Checklist

Make: *ABC Medical*
Brand Name and Model: *VGOOD HCV Antigen Kit version 2.3*

Clause	Essential Principle	Applicable	Method of Conformity	Identity of Specific Documents
General Requirements				
1.	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	*Yes*	1. *The devices are designed and manufactured under a full quality management system in accordance with EN ISO 13485:2016 and presently certified* 2. *The devices are designed and manufactured in conformity with the EU Common Technical Specifications published in OJEC.* 3. *Risk analysis has been performed in accordance with EN ISO 14971:2012. Together with the proactive surveillance studies, it shows that any risks which may be associated with the devices are acceptable when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.*	1. *EN ISO 13485:2016 Certificate No. 012345* 2. *Product Design & Manufacturing files.* 3. *Proactive Surveillance Report PSR-001* 4. *Risk Analysis Report RAR-001*

Draft Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Device

- Alternatively, if the applicants could provide the **Essential Requirements Checklist in accordance with relevant EU IVDMD directives or regulations** and have sufficient evidence that their products also comply with the MDACS requirements, they may submit the Essential Requirements Checklist and a Essential Principles Declaration of Conformity (refer to Appendix III of this Guidance Notes for sample) in lieu of the MDIVD-CCL.

ESSENTIAL REQUIREMENTS CHECKLIST

File No.	[redacted]
Rev. No.	0
Rev. Date	2009.10.29
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Essential Requirements	A-N/A	Standards	Manufactures and Compliance	Locations
I.GENERAL REQUIREMENTS				
1. The devices must be designed and manufactured in such a way that, when user under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of user or, where applicable other persons provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of health and safety.	A	*EN ISO 14971* *EN ISO 14155-1* *EN ISO 14534* *EN ISO 14729* *EN ISO 14730* *EN ISO 14971* *EN ISO 13485*	*- Risk management report(NVTC-210-RM)* *- Product standard(NEO-SOL-004)* *- Quality manual and procedures* *- Test reports(MSK191~ MSK-195)*	*QM Dept.*
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. in selecting the most appreciate solutions, the manufacturer must apply the following principles in the following order -eliminate or reduce risks as far as possible(inherently safe design and construction) -where appropriate take adequate protection measures including alarms if necessary, in relation to risks that must not be eliminated. -inform users of the residual risks due to any shortcomings of the protection measures adopted.	A	*EN ISO 14971* *EN ISO 14155-1* *EN ISO 13485* *EN ISO 14534* *EN ISO 14729* *EN ISO 14730*	*- Risk management report(NVTC-210-RM)* *- Clinical Evaluation Report (NVTC-210-CER)* *- Product standard(NEO-SOL-004)* *- Quality manual and procedures* *- Labeling and Packaging Instruction (NEO-SOL-WS Series)* *- Test reports (MSK191~ MSK-195)*	*QM Dept.*
3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1(a) as specified by the manufacturer.	A	*EN ISO 14971* *EN ISO 13485* *EN ISO 14534* *EN ISO 14729* *EN ISO 14730*	*- Risk management report(NVTC-210-RM)* *- Product standard(NEO-SOL-004)* *- Labeling and Packaging Instruction (NEO-SOL-WS SERIES)* *- Test reports (MSK191~ MSK-195)*	*QM Dept.*
4. The characteristics and performance referred to in Selection 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which must be occur during normal conditions of use.	*A*	*EN ISO 14971* *EN ISO 14155-1* *EN ISO 13485* *EN ISO 14534* *EN ISO 14729* *EN ISO 14730*	*- Risk management report(NVTC-210-RM)* *- Clinical Evaluation Test(NVTC-210-CER)* *- Product standard(NEO-SOL-004)* *- Quality manual and procedures* *- Test reports (MSK191~ MSK-195)*	*QM Dept.*

GN-06,
Appendix 3

Essential Principles Declaration of Conformity

<Name of Manufacturer/Local Responsible Person>

<Address of Manufacturer/Local Responsible Person>

<Date>

Medical Device Control Office,

Department of Health,

Room 604, 6/F, CityPlaza Three,
14 Taikoo Wan Road,
Taikoo Shing,
Hong Kong

Dear Sirs

Product: <Make> <Brand Name and Model(s)>

<Product Description>

Manufactured by <Manufacturer>

<Address of Manufacturer>

We declare that the captioned product fully complies with all the relevant clauses stipulated under the Essential Principles of Safety and Performance of Medical Devices as required under the Medical Device Administrative Control System. We undertake to provide the necessary evidence to demonstrate the compliance within two weeks upon request.

Yours faithfully

<Signature>

<Name and Title>

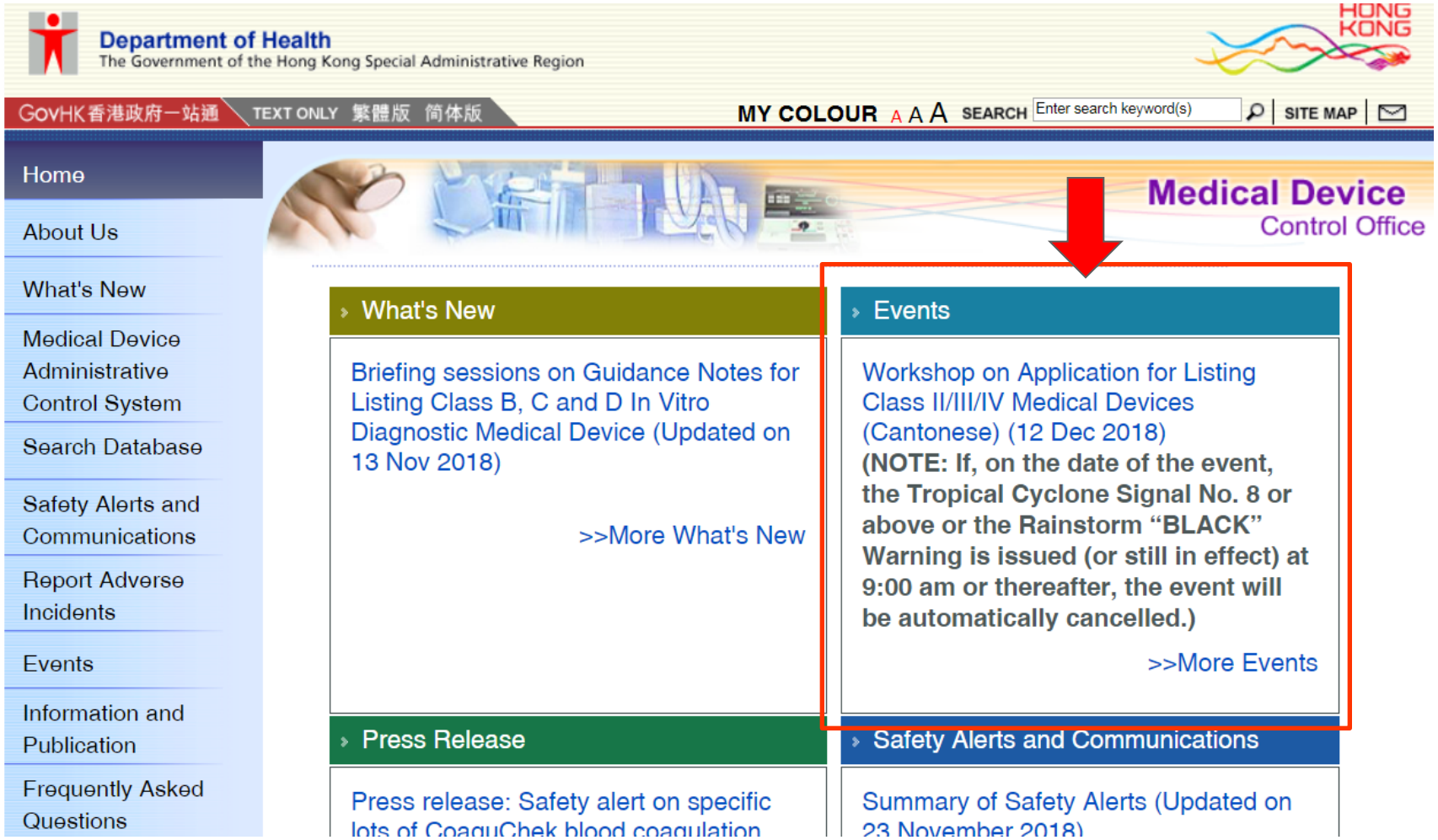
<Company Name>

Listing Class B, C and D In Vitro Diagnostic Medical Device

- Medical Device Control Office arranges interactive workshop from time to time to help traders in submitting applications to list Class B/C/D IVDMD under the Medical Device Administrative Control System.

  - Workshop Content:
    - Medical Device Administrative Control System (MDACS)
    - Local Responsible Person（LRP）
    - Classification of IVDMD
    - How to prepare application documents

Listing Class B, C and D In Vitro Diagnostic Medical Device



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http://www.mdco.gov.hk/english/mdacs/mdacs_aiiml/mdacs_a

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Q&A

Thank you!