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醫療儀器的規管



Regulation of
Medical Devices

Classification Rules for Medical Devices

Technical Reference: TR-003



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Department of Health

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

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1. Introduction

This document is adapted from the GHTF document GHTF/SG1-N15:2006 for the principles of medical devices classification in accordance with the requirements of the Medical Device Administrative Control System (MDACS). The MDACS classifies medical devices other than *in vitro* diagnostic medical device into four classes (Class I, II, III and IV) according to the rules which are interpreted in Section 7 of this document.

2. Scope

This document applies to all products that fall within the scope of the MDACS (please refer to the Guidance Notes GN-01: *Overview of the Medical Device Administrative Control System*).

3. Definitions and Abbreviations

– This booklet shall be read in conjunction with the Guidance Notes GN-00: *Definitions and Abbreviations for the Medical Device Administrative Control System* for the latest definitions and abbreviations of the terms used.

4. General Principles

Regulatory controls are intended to safeguard the health and safety of patients, users and other persons by ensuring that manufacturers of medical devices follow specified procedures during design, manufacture and marketing.

Regulatory controls should be proportional to the level of risk associated with a medical device. The level of regulatory control should increase with increasing degree of risk, taking account of the benefits offered by use of the device. At the same time, the imposition of regulatory controls should not place an unnecessary burden on regulators or manufacturers. Therefore, there is a need to classify medical devices based on their risk to patients, users and other persons.

The risk presented by a particular device depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design, manufacture and use. It also depends, in part, on its intended user(s), its mode of operation, and/or technologies. In general, the classification rules are intended to accommodate new technologies.

5. Recommendations

5.1 Primary Recommendation

The manufacturer should document its justification for placing its product into a particular risk class, including the resolution of any matters of interpretation where it has asked a Conformity Assessment Body and/or MDCO for a ruling.

5.2 Factors Influencing Device Classification

A number of factors, including for example the duration of device contact with the body, the degree of invasiveness, whether the device delivers medicinal products or energy to the patient, whether they are intended to have a biological effect on the patient and local *versus* systemic effects may, alone or in combination, affect device classification.

If, based on the manufacturer's intended purpose, two or more classification rules apply to the device, the device is allocated the highest level of classification indicated.

Where one medical device is intended to be used together with another medical device, that may or may not be from the same manufacturer, the classification rules should apply separately to each of the devices.

Classification of an assemblage of medical devices that individually comply with all MDACS requirements depends on the manufacturer's purpose in packaging and marketing such a combination of separate devices. For example:

- If the combination results in a product that is intended by the manufacturer to meet a purpose different from that of the individual medical devices that make it up, the combination is a new medical device in its own right and should be classified according to the new intended use.
- If the combination is for the convenience of the user but does not change the intended uses of the individual medical devices that make it up, the classification allocated to the assemblage for the purpose of a Declaration of Conformity is at the level of the highest classified device included within it.

If one or more of the medical devices that is in the assemblage has yet to comply with all the relevant regulatory requirements, the combination should be classified as a whole according to its intended use.

Accessories intended specifically by manufacturers to be used together with a ‘parent’ medical device to enable that medical device to achieve its intended purpose, should be subject to all MDACS documents as apply to the medical device itself. For classification purposes an accessory may be classified as though it is a medical device in its own right.

While most software is incorporated into the medical device itself, some is not. Provided such standalone software falls within the scope of the definition for a ‘medical device’, it should be classified as follows:

- Where it drives or influences the use of a separate medical device, it should be classified according to the intended use of the combination.
- Where it is independent of any other medical device, it is classified in its own right using the rules in Section 7 of this document.
- Stand alone software (to the extent it falls within the definition of a medical device) is deemed to be an active device.

5.3 General Classification System for Medical Devices

Figure 1 indicates the four risk classes of devices. The examples given are for illustration only and the manufacturer must apply the classification rules to each medical device according to its intended purpose.

Figure 1: General classification system for medical devices

CLASS	RISK LEVEL	DEVICE EXAMPLES
I	Low Risk	Surgical retractors / tongue depressors
II	Low-moderate Risk	Hypodermic Needles / suction equipment
III	Moderate-high Risk	Lung ventilator / bone fixation plate
IV	High Risk	Heart valves / implantable defibrillator

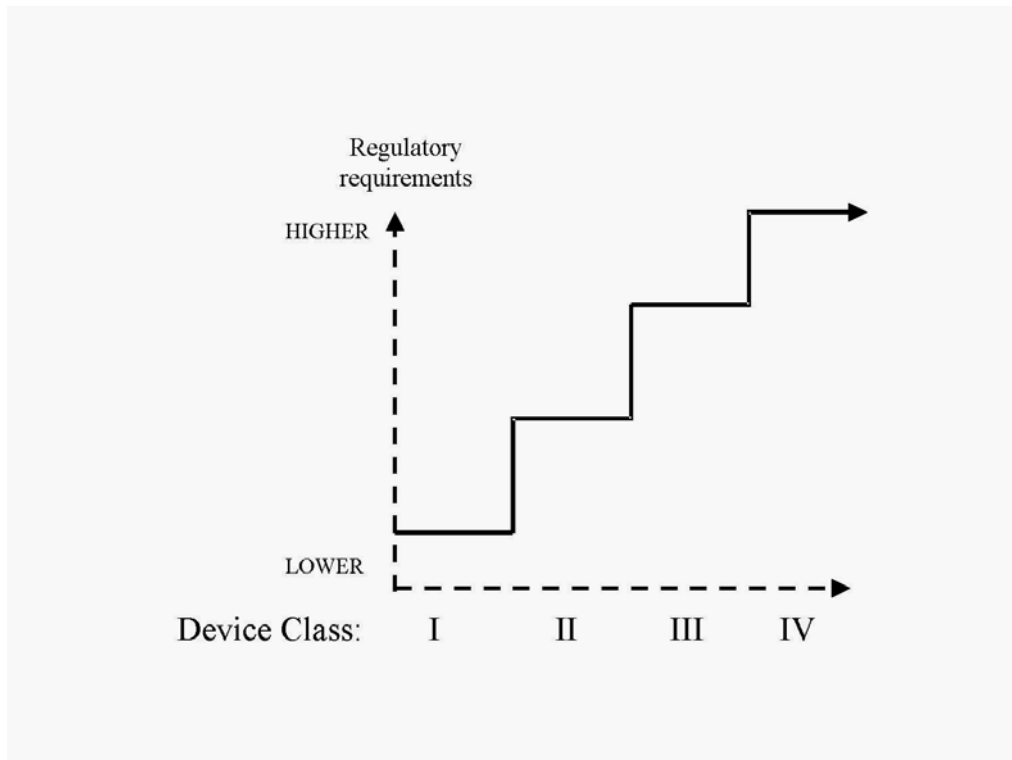
Figure 2 shows a conceptual illustration of increasing levels of regulatory requirements as the device risk class increases. These regulatory controls may include, for example:

- technical data;
- product testing using in-house or independent resources;
- the need for and frequency of independent external audit of the manufacturer’s quality system; and

- independent external review of the manufacturer's technical data.

The concept is expanded in our Technical Reference TR-001 entitled *Principles of Conformity Assessment for Medical Devices*.

Figure 2: Conceptual illustration of regulatory controls increasing with device risk class



6. The Determination of Device Class

The manufacturer should:

1. Decide if the product concerned is a medical device, using the appropriate definition (See Section 3).

NOTE: Medical devices that are used for the *in vitro* examination of specimens derived from the human body are not covered by the classification rules within this document.

2. Document the intended use of the medical device.
3. Take into consideration all the rules that follow in order to establish the proper classification for the device, noting that **where a medical device has features that place it into more than one class, classification and conformity assessment should be based on the highest class indicated.**
4. Determine if the device is subject to any special rules.

7. Classification Rules for Medical Devices^a

The actual classification of each device depends on the precise claims made by the manufacturer and on its intended use. While the provision of examples in the table that follows is helpful when

^a These have been adopted from [1]. Classes I, II, III and IV are referred to respectively as Classes A, B, C and D in [1].

interpreting the purpose of each rule, it must be emphasized that the actual classification of a particular device must be considered individually, taking account of its design and intended use.

Where a medical device has features that place it into more than one class, conformity assessment should be based on the highest class indicated.

RULE	ILLUSTRATIVE EXAMPLES OF DEVICES THAT MAY CONFORM WITH A RULE
➤ <i>NON-INVASIVE DEVICES</i>	
<p>Rule 1. All non-invasive devices which come into contact with injured skin:</p>	<p>Devices covered by this rule are extremely claim sensitive.</p>
<p>- are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only, i.e. they heal by primary intent;</p>	<p><u>Examples:</u> simple wound dressings; cotton wool.</p>
<p>- are in Class II if they are intended to be used principally with wounds which have breached the dermis, including devices principally intended to manage the microenvironment of a wound.</p>	<p><u>Examples:</u> non-medicated impregnated gauze dressings.</p>
<p>unless they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class III.</p>	<p>Devices used to treat wounds where the subcutaneous tissue is at least partially exposed and the edges of the wound are not sufficiently close to be pulled together. To close the wound, new tissue must be formed within the wound prior to external closure. The device manufacturer claims that they promote healing through physical methods other than 'primary intent'. <u>Examples:</u> dressings for chronic ulcerated wounds; dressings for severe burns.</p>
<p>Rule 2. All non-invasive devices intended for channelling or storing</p> <ul style="list-style-type: none"> • body liquids or tissues, • liquids or • gases <p>for the purpose of eventual infusion, administration or introduction into the body are in Class I,</p>	<p>Such devices are 'indirectly invasive' in that they channel or store liquids that will eventually be delivered into the body (see comment for Rule 4). <u>Examples:</u> administration sets for gravity infusion; syringes without needles.</p>
<p>unless they may be connected to an active medical device in Class II or a higher class, in which case they are Class II;</p>	<p><u>Examples:</u> syringes and administration sets for infusion pumps; anaesthesia breathing circuits. NOTE: "Connection" to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-active device and vice versa.</p>
<p>unless they are intended for use of channeling blood, or storing or channeling other body liquids, or for storing organs, parts of organs or body tissues, in which case they are Class II.</p>	<p><u>Examples:</u> tubes used for blood transfusion, organ storage containers.</p>

unless they are blood bags, in which case they are Class III.	<u>Example:</u> Blood bags that do not incorporate an anti-coagulant.
Rule 3. All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids, or other liquids intended for infusion into the body are in Class III,	Such devices are indirectly invasive in that they treat or modify substances that will eventually be delivered into the body (see note to comment for Rule 4). They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. <u>Examples:</u> haemodialyzers; devices to remove white blood cells from whole blood. NOTE: for the purpose of this part of the rule, 'modification' does not include simple, mechanical filtration or centrifuging which are covered below.
unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class II.	<u>Examples:</u> devices to remove carbon dioxide; particulate filters in an extracorporeal circulation system.
Rule 4. All other non-invasive devices are in Class I.	These devices either do not touch the patient or contact intact skin only. <u>Examples:</u> urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.
➤ INVASIVE DEVICES	
Rule 5. All invasive devices with respect to body orifices (other than those which are surgically invasive) and which: • are not intended for connection to an active medical device, or • are intended for connection to a Class I medical device only.	Such devices are invasive in body orifices and are not surgically invasive. Devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynaecology. Classification depends on the duration of use and the sensitivity (or vulnerability) of the orifice to such invasion.
- are in Class I if they are intended for transient use;	<u>Examples:</u> examination gloves; enema devices.
- are in Class II if they are intended for short-term use;	<u>Examples:</u> urinary catheters, tracheal tubes.
unless they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class I,	<u>Examples:</u> dentures intended to be removed by the patient; dressings for nose bleeds.
- are in Class III if they are intended for long-term use;	<u>Example:</u> urethral stent; contact lenses for long-term continuous use (for this device, removal of the lens for cleaning or maintenance is considered as part of the continuous use).
unless they are intended for long-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear-drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class II.	<u>Examples:</u> orthodontic wire, fixed dental prosthesis.
All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class II or a higher class, are in Class II.	<u>Examples:</u> tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips. NOTE: independent of the time for which they are invasive.
Rule 6. All surgically invasive devices intended for transient use are in Class II,	A majority of such devices fall into several major groups: those that create a conduit through the skin (e.g.

	<p>syringe needles; lancets), surgical instruments (e.g. single-use scalpels; surgical staplers; single-use aortic punch); surgical gloves; and various types of catheter/sucker etc.</p> <p>NOTE: a surgical instrument (other than those in Class IV) is in Class I if reusable and in Class II if supplied sterile and intended for single use. Also, a surgical instrument connected to an active device is in a higher class than I.</p> <p>NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.</p>
<p>unless they are reusable surgical instruments, in which case they are in Class I; or</p>	<p>Examples: Manually operated surgical drill bits and saws.</p>
<p>unless intended to supply energy in the form of ionizing radiation, in which case they are in Class III; or</p>	<p>Example: catheter incorporating/containing sealed radioisotopes.</p>
<p>unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class III; or</p>	<p>NOTES: (a) the ‘biological effect’ referred to is an intended one rather than unintentional. The term ‘absorption’ refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.</p> <p>(b) This part of the rule does not apply to those substances that are excreted without modification from the body.</p> <p>Example: Insufflation gases for the abdominal cavity.</p>
<p>unless intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class III; or</p>	<p>Example: insulin pen for self-administration.</p> <p>NOTE: the term ‘administration of medicines’ implies storage and/or influencing the rate/volume of medicine delivered not just channelling. The term ‘potentially hazardous manner’ refers to the characteristics of the device and not the competence of the user.</p>
<p>unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class IV; or</p>	
<p>unless intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class IV.</p>	<p>Examples: angioplasty balloon catheters and related guide wires; dedicated disposable cardiovascular surgical instruments.</p>
<p>Rule 7. All surgically invasive devices intended for short-term use are in Class II,</p>	<p>Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types.</p> <p>Examples: infusion cannulae; temporary filling materials; non-absorbable skin closure devices; tissue stabilisers used in cardiac surgery.</p> <p>NOTE: includes devices that are used during cardiac surgery but do not monitor or correct a defect.</p> <p>NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.</p>
<p>unless they are intended to administer medicinal products, in which case they are in Class III; or</p>	<p>NOTE: the term ‘administration of medicines’ implies storage and/or influencing the rate/volume of medicine</p>

	delivered not just channelling.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class III; or	<u>Example:</u> surgical adhesive.
unless they are intended to supply energy in the form of ionizing radiation, in which case they are in Class III; or	<u>Example:</u> brachytherapy device.
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class IV; or	<u>Example:</u> absorbable suture; biological adhesive. NOTE: the 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.
unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class IV;	<u>Example:</u> neurological catheter.
unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class IV.	<u>Examples:</u> cardiovascular catheters; temporary pacemaker leads; carotid artery shunts.
Rule 8. All implantable devices, and long-term surgically invasive devices, are in Class III,	Most of the devices covered by this rule are implants used in the orthopaedic, dental, ophthalmic and cardiovascular fields. <u>Example:</u> maxilla-facial implants; prosthetic joint replacements; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating). NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.
unless they are intended to be placed into the teeth, in which case they are in Class II; or	<u>Examples:</u> bridges; crowns; dental filling materials.
unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class IV; or	<u>Examples:</u> prosthetic heart valves; spinal and vascular stents.
unless they are intended to be life supporting or life sustaining, in which case they are in Class IV; or	
unless they are intended to be active implantable medical devices, in which case they are Class IV; or	<u>Example:</u> pacemakers, their electrodes and their leads; implantable defibrillators.
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class IV; or	<u>Example:</u> implants claimed to be bioactive. NOTE: hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.
unless they are intended to administer medicinal products, in which case they are in Class IV; or	<u>Example:</u> rechargeable non-active drug delivery system.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class IV; or	NOTE: bone cement is not within the scope of the term 'chemical change in the body' since any change takes place in the short rather than long term.

<p>unless they are breast implants, in which case they are in Class IV.</p>	
<p>➤ ACTIVE DEVICES</p>	
<p>Rule 9(i). All active therapeutic devices intended to administer or exchange energy are in Class II,</p>	<p>Such devices are mostly electrically powered equipment used in surgery; devices for specialised treatment and some stimulators. <u>Examples:</u> muscle stimulators; TENS devices; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy.</p>
<p>unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class III.</p>	<p><u>Examples:</u> lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; therapeutic X-ray and other sources of ionizing radiation. NOTE: the term ‘potentially hazardous’ refers to the type of technology involved and the intended application.</p>
<p>Rule 9(ii). All active devices intended to control or monitor the performance of active therapeutic devices in Class III, or intended directly to influence the performance of such devices, are in Class III.</p>	<p><u>Examples:</u> external feedback systems for active therapeutic devices.</p>
<p>Rule 10(i). Active devices intended for diagnosis are in Class II:</p>	<p>Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals, interventional radiology and diagnostic radiology.</p>
<p>- if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class I), or</p>	<p><u>Examples:</u> magnetic resonance equipment; diagnostic ultrasound in non-critical applications; evoked response stimulators.</p>
<p>- if they are intended to image <i>in vivo</i> distribution of radiopharmaceuticals, or</p>	<p><u>Example:</u> gamma/nuclear cameras.</p>
<p>- if they are intended to allow direct diagnosis or monitoring of vital physiological processes,</p>	<p><u>Example:</u> electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs.</p>
<p>unless they are specifically intended for:</p> <p>a) monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, or</p> <p>b) diagnosing in clinical situations where the patient is in immediate danger,</p> <p>in which case they are in Class III.</p>	<p><u>Example:</u> monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors. <u>Example:</u> ultrasound equipment for use in interventional cardiac procedures.</p>
<p>Rule 10(ii). Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class III.</p>	<p><u>Example:</u> these include devices for the control, monitoring or influencing of the emission of ionizing radiation.</p>
<p>Rule 11. All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class II,</p>	<p>Such devices are mostly drug delivery systems or anaesthesia equipment. <u>Examples:</u> suction equipment; feeding pumps; jet</p>

	injectors for vaccination; nebuliser to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous.
unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration, in which case they are in Class III.	Examples: infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers; nebuliser where the failure to deliver the appropriate dosage characteristics could be hazardous.
Rule 12. All other active devices are in Class I.	Examples: examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.
➤ ADDITIONAL RULES	
Rule 13. All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class IV.	These medical devices incorporate medicinal substances in an ancillary role. Examples: antibiotic bone cements; heparin-coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound; blood bags incorporating an anti-coagulant. NOTE: Such medical devices may be subject to additional conformity assessment procedures according to the Pharmacy and Poisons Ordinance (Cap.138), the Antibiotics Ordinance (Cap. 137) and the Dangerous Drugs Ordinance (Cap. 134).
Rule 14. All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are Class IV,	NOTE: Please note that the following products do not fall within the current scope of the MDACS and will not be listed at this stage: 1. devices that incorporate human blood, blood products, plasma or blood cells of human origin, except for stable derivatives devices; 2. transplants or tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin 3. transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissues.
unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only, where they are in Class I.	Examples: leather components of orthopaedic appliances.
Rule 15. All devices intended specifically to be used for sterilising medical devices, or disinfecting as the end point of processing, are in Class III.	Examples: devices for disinfecting or sterilising endoscopes; disinfectants intended to be used with medical devices. NOTE: This rule does not apply to products that are intended to clean medical devices by means of physical action e.g. washing machines.
unless they are intended for disinfecting medical	Example: washer disinfectors.

devices prior to end point sterilisation or higher level disinfection, in which case they are in Class II; or	
unless they are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses, in which case they are in Class III.	<u>Example:</u> contact lens solutions.
Rule 16. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class III,	<u>Examples:</u> condoms; contraceptive diaphragms.
unless they are implantable or long-term invasive devices, in which case they are in Class IV.	<u>Example:</u> intrauterine contraceptive device.

8. Enquiries

Enquiries concerning this booklet and the MDACS should be directed to:

Medical Device Control Office,

Department of Health.

Facsimile number: 3157 1286

Telephone number: ~~2961 8788~~ 3107 8484

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

E-mail address: mdco@dh.gov.hk

All latest versions of published documents and application forms for MDACS are available at MDCO website.

9. References

- [1] Global Harmonization Task Force: *Principles of Medical Devices Classification* Final Document SG1/N15:2006
- [2] Department of Health. *Overview of the Medical Device Administrative Control System* Guidance Note GN-01
- [3] Department of Health. *Definitions and Abbreviations for the Medical Device Administrative Control System* Guidance Note GN-00