Classification Rules for Medical Devices

Technical Reference: TR-003

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*) and to the activities of the medical device manufacturer.

3. **Definitions and Abbreviations**

Given below are the definitions and abbreviations of some of the terms which will appear in this booklet -

3.1 **Active medical device** means a device whose operation depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices.

3.2 **Active therapeutic device** means an active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

3.3 **Active device intended for diagnosis** means an active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or to support in treating physiological conditions, states of health, illnesses or congenital deformities.

3.4 **Active implantable medical device** means any active medical device, together with any accessories for its proper functioning, which is intended to be totally or partially introduced,
surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

3.5 **Body orifice** means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.

3.6 **Central circulatory system** means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, carotid arteries (common, internal and external), cerebral arteries, brachiocephalic artery, aorta (includes all segments of the aorta), inferior and superior vena cava and common iliac arteries.

3.7 **Central nervous system** means brain, meninges and spinal cord.

3.8 **GHTF** stands for Global Harmonization Task Force, which was formed in 1992 by a group of representatives from regulatory authorities and medical device industry. The aim of the GHTF is to harmonize the standards and principles for the regulation of medical devices. The founding members of the GHTF are the USA, the EU, Canada, Australia, and Japan.

3.9 **Harm** means physical injury or damage to the health of people or damage to property or the environment.

3.10 **Hazard** means potential source of harm.

3.11 **Immediate danger** means a situation where the patient is at risk of either losing life or an important physiological function if no immediate preventative measure is taken.

3.12 **Implantable medical device** means any device, including those that are partially or wholly absorbed, which is intended –
(a) to be totally introduced into the human body or,
(b) to replace an epithelial surface or the surface of the eye, 
by surgical intervention which is intended to remain in place after the procedure.
Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

3.13 **Intended use/purpose** means use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.
3.14 **Invasive device** means a device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

3.15 **Life supporting or life sustaining** means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

3.16 **Long-term** means “normally intended for continuous use for more than 30 days”.

3.17 **MDACS** stands for Medical Device Administrative Control System.

3.18 **MDCO** stands for Medical Device Control Office.

3.19 **Medical device** means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of—

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease; or
(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury; or
(c) investigation, replacement, modification, or support of the anatomy or of a physiological process; or
(d) supporting or sustaining life; or
(e) control of conception (including contraception); or
(f) disinfection of medical devices; or
(g) providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body;

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means.

3.20 **Reusable surgical instrument** means instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or other surgical procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures for cleaning and/or sterilisation have been carried out.

3.21 **Risk** means combination of the probability of occurrence of harm and the severity of that harm.
3.22 **Short-term** means “normally intended for continuous use for between 60 minutes and 30 days”.

3.23 **Surgically invasive device** means an invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

3.24 **Transient use** means “normally intended for continuous use for less than 60 minutes”.

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**

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

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*. 
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 special national rules that apply within a particular jurisdiction.

NOTES:

Once a rules-based system has been adopted, modifications may occasionally be required. For example, where through post-market experience, a level of risk for a type of medical device, classified using the criteria found in this guidance document is no longer appropriate, consideration should be given to re-classification of the device type by a change to the rules.
7. **Classification Rules for Medical Devices**

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 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.

<table>
<thead>
<tr>
<th>RULE</th>
<th>ILLUSTRATIVE EXAMPLES OF DEVICES THAT MAY CONFORM WITH A RULE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NON-INVASIVE DEVICES</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Rule 1.</strong> All non-invasive devices which come into contact with injured skin:</td>
<td>Devices covered by this rule are extremely claim sensitive.</td>
</tr>
<tr>
<td>- 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;</td>
<td>Examples: simple wound dressings; cotton wool.</td>
</tr>
<tr>
<td>- 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 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.</td>
<td>Examples: non-medicated impregnated gauze dressings.</td>
</tr>
<tr>
<td><strong>Rule 2.</strong> All non-invasive devices intended for channelling or storing body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class I unless they may be connected to an active medical device in Class II or a higher class, in which case they</td>
<td>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). Examples: administration sets for gravity infusion; syringes without needles.</td>
</tr>
</tbody>
</table>

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*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].
are Class II;

**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.

**Examples:** tubes used for blood transfusion, organ storage containers.

**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.

**Example:** 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, unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class II.

**Examples:** 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** they are blood bags, in which case they are Class III.

**Rule 4.** All other non-invasive devices are in Class I. These devices either do not touch the patient or contact intact skin only.

**Examples:** 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.

- are in Class I if they are intended for transient use;
- are in Class II if they are intended for short-term use;

**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.

- are in Class III if they are intended for long-term 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 removed by the patient; dressings for nose bleeds.

**Examples:** examination gloves; enema devices.

**Examples:** urinary catheters, tracheal tubes.

**Examples:** dentures intended to be removed by the patient; dressings for nose bleeds.

**Examples:** 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).

**Examples:** orthodontic wire, fixed dental prosthesis.
absorbed by the mucous membrane, in which case they are in Class II.

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.

**Examples:** 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,

| unless they are reusable surgical instruments, in which case they are in Class I; or |
| unless intended to supply energy in the form of ionizing radiation, in which case they are in Class III; or |
| unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class III; or |

A majority of such devices fall into several major groups: those that create a conduit through the skin (e.g. 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.

**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.

**NOTE:** if the device incorporates a medicinal substance in a secondary role refer to Rule 13.

**Examples:** Manually operated surgical drill bits and saws.

**Example:** catheter incorporating/containing sealed radioisotopes.

**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.

(b) This part of the rule does not apply to those substances that are excreted without modification from the body.

**Example:** Insufflation gases for the abdominal cavity. **Example:** insulin pen for self-administration.

**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.

| unless intended specifically for use in direct contact with the central nervous system, in which case they are in Class IV; or |
| 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. |

Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types.

| Rule 7. All surgically invasive devices intended for short-term use are in Class II, |

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### Rule 8. All implantable devices, and long-term surgically invasive devices, are in Class III.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Examples</th>
<th>Notes/Exceptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>unless they are intended to administer medicinal products, in which case they are in Class III; or</td>
<td>Examples: infusion cannulae; temporary filling materials; non-absorbable skin closure devices; tissue stabilisers used in cardiac surgery. <strong>NOTE:</strong> includes devices that are used during cardiac surgery but do not monitor or correct a defect. <strong>NOTE:</strong> if the device incorporates a medicinal substance in a secondary role refer to Rule 13.</td>
<td></td>
</tr>
<tr>
<td>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</td>
<td>Example: surgical adhesive. <strong>NOTE:</strong> the term ‘administration of medicines’ implies storage and/or influencing the rate/volume of medicine delivered not just channelling.</td>
<td></td>
</tr>
<tr>
<td>unless they are intended to supply energy in the form or ionizing radiation, in which case they are in Class III; or</td>
<td>Example: brachytherapy device. <strong>NOTE:</strong> if the device incorporates a medicinal substance in a secondary role refer to Rule 13.</td>
<td></td>
</tr>
<tr>
<td>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</td>
<td>Example: absorbable suture; biological adhesive. <strong>NOTE:</strong> 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.</td>
<td></td>
</tr>
<tr>
<td>unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class IV;</td>
<td>Example: neurological catheter.</td>
<td></td>
</tr>
</tbody>
</table>
to be wholly or mainly absorbed, in which case they are
in Class IV; or

**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

Example: 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.

**unless** they are breast implants, in which case they are
in Class IV.

### ACTIVE DEVICES

**Rule 9(i).** All active therapeutic devices intended to
administer or exchange energy are in Class II,

Such devices are mostly electrically powered
equipment used in surgery; devices for specialised
treatment and some stimulators.

**Examples:** muscle stimulators; TENS devices; powered
dental hand pieces; hearing aids; neonatal phototherapy
equipment; ultrasound equipment for physiotherapy.

**NOTE:** the term 'potentially hazardous' refers to the
type of technology involved and the intended
application.

**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.

**Examples:** lung ventilators; baby incubators;
electrosurgical generators; external pacemakers and
defibrillators; surgical lasers; lithotriptors; therapeutic
X-ray and other sources of ionizing radiation.

**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.

**Examples:** external feedback systems for active
therapeutic devices.

**Rule 10(i).** Active devices intended for diagnosis are in
Class II:

- 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

  **Examples:** magnetic resonance equipment; diagnostic
  ultrasound in non-critical applications; evoked response
  stimulators.

- if they are intended to image *in vivo* distribution of
  radiopharmaceuticals, or

  **Example:** gamma/nuclear cameras.

- if they are intended to allow direct diagnosis or
  monitoring of vital physiological processes,

  **Example:** electronic thermometers, stethoscopes and
  blood pressure monitors; electrocardiographs.

**unless** they are specifically intended for:

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

b) diagnosing in clinical situations where the patient is
in immediate danger,
in which case they are in Class III.

**Example:** monitors/alarms for intensive care; biological
sensors; oxygen saturation monitors; apnoea monitors.

**Example:** ultrasound equipment for use in
interventional cardiac procedures.
**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.

**Example:** these include devices for the control, monitoring or influencing of the emission of ionizing radiation.

**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, 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:** suction equipment; feeding pumps; jet 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.

**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, unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only.

**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 or animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissues.

**Examples:** leather components of orthopaedic appliances.
where they are in Class I.

| 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. | Example: washer disinfectors. |
| unless they are intended for disinfecting medical 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. | Example: contact lens solutions. |

Rule 16. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class III, unless they are implantable or long-term invasive devices, in which case they are in Class IV. Examples: condoms; contraceptive diaphragms. Example: 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
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
