6.2 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 medicines or energy to the patient, whether they are intended to have a biological affect on the patient and local *versus* systemic effects (e.g. conventional *versus* absorbable sutures) may, alone or in combination, affect device classification.

Where more than one of the classification rules applies to the medical device, it should be allocated to the highest class 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, (e.g. a physiological monitor and a separate recorder, or a general purpose syringe and a syringe driver), the classification rules should apply separately to each of the devices.

Classification of an assemblage of medical devices that individually comply with all regulatory 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 (e.g. a customised kit that provides all the devices necessary to carry out a particular surgical procedure) there is no need to classify the combination as a whole although the manufacturer may do so if it wishes.

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.

An accessory to a medical is not considered to be a medical device but is classified separately from its 'parent' device. NOTE: components and spare parts of medical devices are not considered accessories.

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 will have the same class as the device itself.
- Where it is independent of any other medical device, it is classified in its own right using the rules in Section 8.0 of this document.

At this time, conformity assessment requirements and other regulatory controls assigned to each class of device by different Regulatory Authorities have yet to be harmonized and may

vary. While Study Group 1 of GHTF continues to support and encourage regulatory harmonization, it recognises that some Regulatory Authorities may have to reflect different local needs when they introduce new regulations on classification, for example, in the application of devices covered by the Additional Rules 13 to 16. Study Group 1 hopes any such differences will disappear in the course of time.

6.3 Proposed 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: Proposed general classification system for medical devices

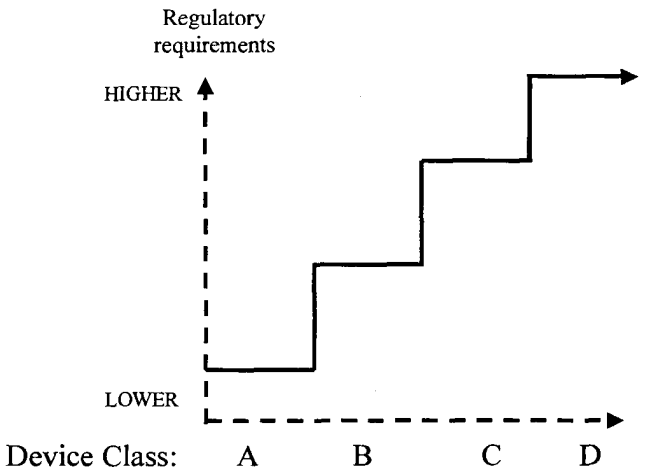
CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Risk	Surgical retractors / tongue depressors
B	Low-moderate Risk	Hypodermic Needles / suction equipment
C	Moderate-high Risk	Lung ventilator / orthopaedic implants
D	High Risk	Heart valves / implantable defibrillator

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:-

- operation of a quality system (recommended for all devices);
- documentation of clinical evidence to support the manufacturer's claims;
- 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 the GHTF guidance document entitled *Premarket Conformity Assessment for Medical Devices.*

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



7.0 The Determination of Device Class

The manufacturer should:

1. Decide if the product concerned is a medical device, using *Information Document Concerning the Definition of the Term "Medical Device".*

   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 (see Scope).

2. Determine 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, conformity assessment should be based on the highest class indicated.**

4. Determine that the device is not subject to special national rules that apply within a particular jurisdiction.

NOTE: Where special national rules are applied, resulting in a device class other than that suggested by the present rules, then a different conformity assessment procedure may be indicated. This may have an effect on the acceptability of such devices for free movement in a global context unless other, or additional, conformity assessment procedures are carried out. For example, where such special national rules result in the lower classification of a particular medical device than that indicated in the rules indicated below, and in consequence, a less vigorous conformity assessment procedure/s, this may be unacceptable to other jurisdictions.

8.0 Classification Rules

The examples of medical devices provided in the table below are for illustrative purposes only since the actual classification of each one depends on the precise claims made by the manufacturer and on the intended use.

RULE	EXAMPLES & COMMENTS
➢ ***NON-INVASIVE DEVICES***	
1. All non-invasive devices are in Class A, unless Rule 2, 3 or 4 applies.	These devices either do not touch the patient or contact intact skin only. Examples: urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds. **NOTE:** Non-invasive devices that are indirectly in contact with the body & can influence internal physiological processes by storing, channelling or treating blood, other body liquids or liquids which are returned or infused into the body or by generating energy that is delivered to the body are outside the scope of this rule.
2. All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class A,	Such devices are 'indirectly invasive' in that they channel or store liquids that will eventually be delivered into the body (see comment for Rule 1). Examples: administration sets for gravity infusion; syringes without needles.
unless they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;	Examples: 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.*
unless they are intended for use of	Examples: tubes used for blood

storing or channeling blood or other body liquids or for storing organs, parts of organs or body tissues, in which case they are Class B.	transfusion. **NOTE:** in some jurisdictions, blood bags have a special rule that places them within a higher risk class.
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 C,	Such devices are indirectly invasive in that they treat or modify substances that will eventually be delivered into the body (see comment for Rule 1). They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. Examples: haemodializers; 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 B.	Examples: devices to warm or cool blood; devices to remove carbon dioxide; particulate filters in an extracorporial circulation system.
4. All non-invasive devices which come into contact with injured skin:	Devices covered by this rule are extremely claim sensitive.
- are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;	Examples: simple wound dressings; cotton wool.
unless 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 C.	Devices used to treat wounds where the subcutaneous tissue is as least partially exposed and the edges of the wound are not sufficiently close to be pulled together. The device manufacturer claims that they promote healing through physical methods other than providing a barrier are in Class C. Examples: dressings for chronic ulcerated wounds; dressings for severe burns.
- are in Class B in all other cases, including devices principally intended to manage the microenvironment of a wound.	Examples: non-medicated impregnated gauze dressings.
➢ ***INVASIVE DEVICES***	
5. All invasive devices with respect to body orifices (other than those which are surgically invasive) and which:	Such devices are invasive in body orifices (refer to definition) and are not surgically invasive. Devices tend to be

a) are not intended for connection to an active medical device or b) are intended for connection to a Class A medical device	diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynaecology. Classification depends on the time of invasion and the sensitivity (or vulnerability) of the orifice to such invasion.
- are in Class A if they are intended for transient use;	Examples: dental impression materials; examination gloves; enema devices.
- are in Class B if they are intended for short-term use;	Examples: contact lenses, urinary catheters, tracheal tubes.
unless they are used 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 A,	Examples: dentures intended to be removed by the patient; dressings for nose bleeds.
- are in Class C if they are intended for long-term use;	Example: 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 used 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 B.	Examples: 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 B or a higher class, are in Class B.	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.
6. All surgically invasive devices intended for transient use are in Class B,	A majority of such devices fall into three major groups: those that create a conduit through the skin (e.g. syringe needles; lancets), surgical instruments (e.g. single-use scalpels; surgical staplers; surgical gloves; single-use aortic punch) and various types of catheter /sucker etc. **NOTE**: a surgical instrument (other than those in Class D) is in Class A if reusable and in Class B if supplied sterile and intended for single use. Also, a surgical instrument connected to an active device

	is in a higher class than A. **NOTE:** if the device incorporates a medicinal substance in a secondary role refer to Rule 13.
unless they are reusable surgical instruments, in which case they are in Class A;	Examples: Manually operated surgical drill bits and saws.
unless intended to supply energy in the form of ionizing radiation, in which case they are in Class C;	Example: catheter incorporating/ containing sealed radioisotopes.
unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C;	**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 intended to administer medicines 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 C.	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 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 D.	Examples: angioplasty balloon catheters and related guidewires; dedicated disposable cardiovascular surgical instruments.
7. All surgically invasive devices intended for short-term use are in Class B,	Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types. Examples: clamps; infusion cannulae; temporary filling materials; non-absorbable skin closure devices; tissue stabilisers used in cardiac surgery. **NOTE:** includes devices that are used during cardiac surgery but do not monitor or correct a defect. **NOTE:** if the device incorporates a medicinal substance in a secondary role refer to Rule 13.