

GLOBAL HARMONIZATION TASK FORCE

STUDY GROUP 1

RECOMMENDATION ON MEDICAL DEVICES CLASSIFICATION

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 during marketing.

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.

Regulatory controls should be proportional to the level of risk associated with a medical device. The level of regulatory control should increase with the degree of risk. 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; and
- there is benefit for manufacturers and regulatory authorities if a globally harmonized classification system is developed.

It is recommended that:

- Regulatory Authorities should work towards the establishment of a global classification system.
- Such a system should be based upon common features of existing national requirements with the aim of future convergence.
- This system should consist of four risk classes.
- The determination of class should be based on a set of rules derived from the features that create risk.
- Where exceptions from the classification rules are necessary these should be minimized.

Figure 1 indicates the four risk classes of devices. Figure 2 shows a conceptual illustration of levels of regulatory control that increase in step with the risk class of the device. Table 1 lists a number of questions to help guide the classification of devices by risk. Figure 3 provides decision trees to demonstrate how these parameters might be used to classify specific devices.

Regulatory Authorities that are developing new classification schemes or amending existing ones are encouraged to consider the adoption of this system as this will help to reduce the

diversity of systems worldwide and facilitate the process of harmonization. Regulatory Authorities with existing systems are also encouraged to consider adopting this system.

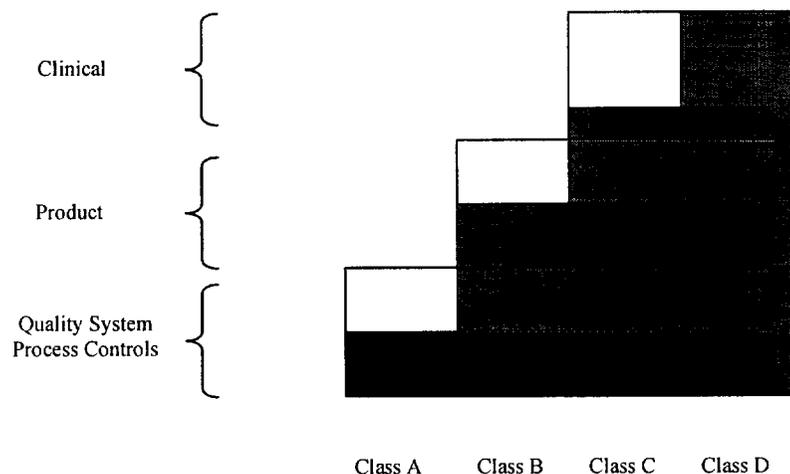
Each Regulatory Authority may assign names or numbers to the risk classes, based on local preference. Regulatory controls assigned to each Class may at this time vary based on current practice.

The recognized level of risk may change based on post-market experience or technological improvements to the device. This may lead to a need for reclassification. Regulatory Authorities are encouraged to include a process for changing the assigned classification of a device, when necessary. Regulatory Authorities are encouraged to consult with their international counterparts when considering reclassification of a device.

Figure 1: Proposed general classification system for medical devices

CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Risk	Simple surgical instruments / tongue depressors
B	Low moderate risk	Hypodermic Needles / suction equipment
C	High moderate risk	Lung ventilator / orthopaedic implants
D	High Risk	Heart valves / implantable defibrillator

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



Note: shading indicates external assessment of increasing intensity with

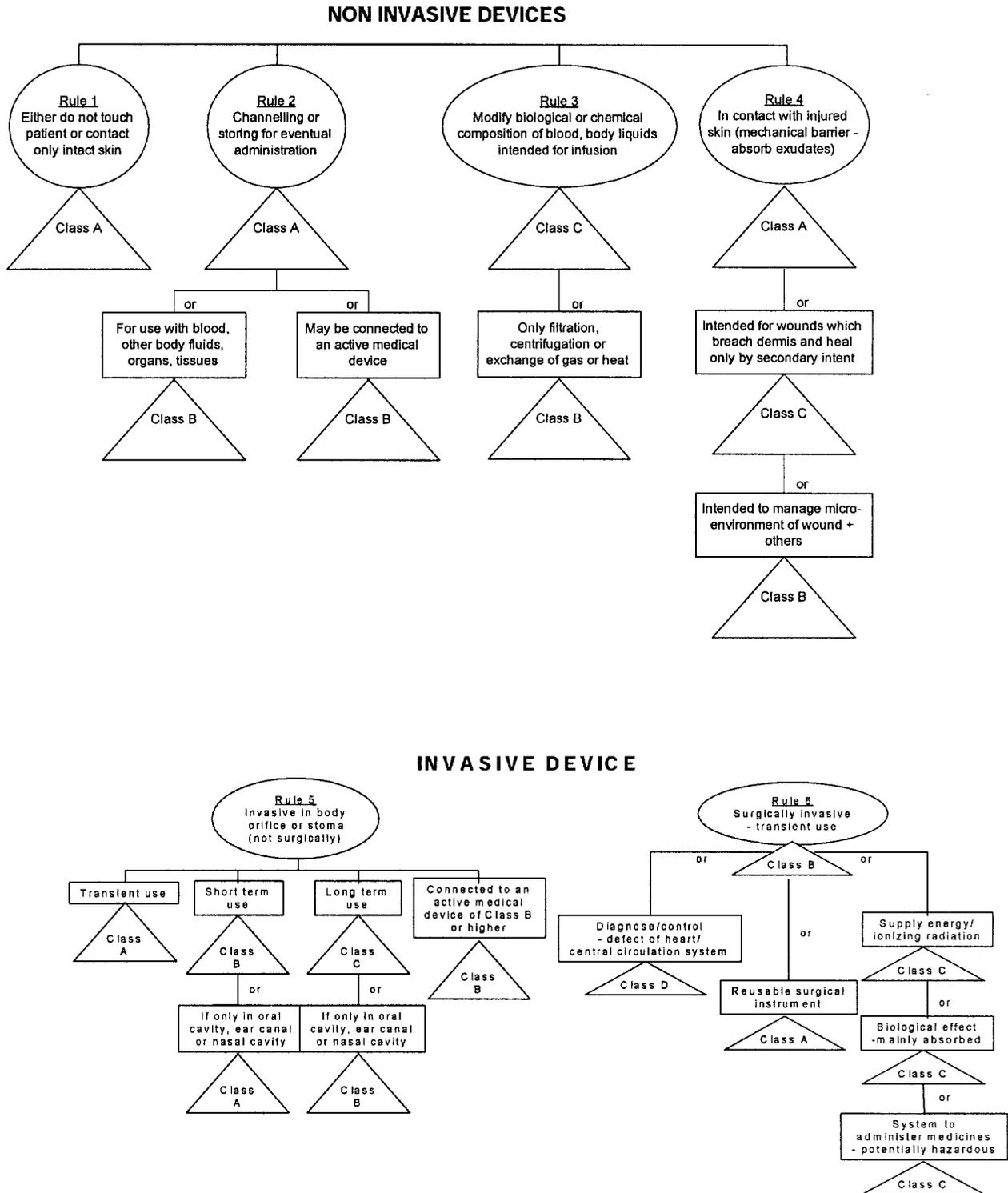
Issues to be considered when classifying devices

The following questions are suggested to help guide the development of risk-based rules for classification.

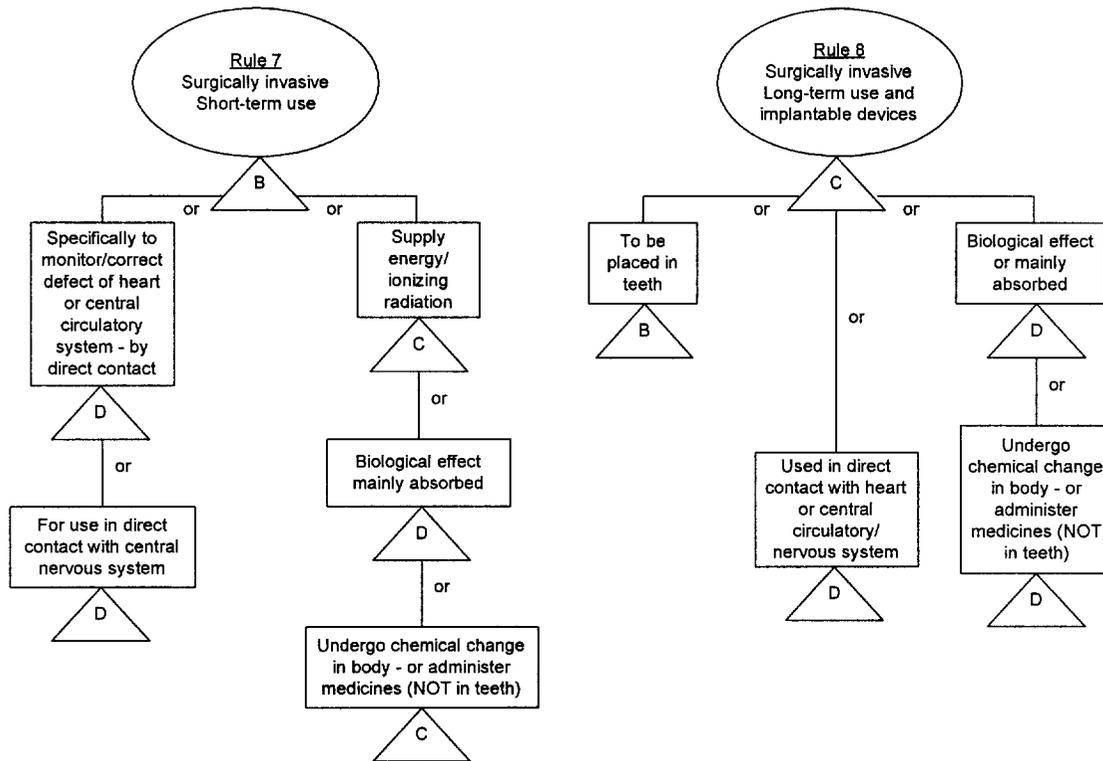
- Is the device intended for therapy or diagnosis?
- Is the device intended for use outside the body, on the body surface, or inside the body?
- Does the device replace or supplement a critical body function?
- How long will an invasive device remain in the body? What is the duration of contact?
- Is the device likely to contact critical organs of the body?
- Does the device enter through a natural body orifice or is it introduced in the course of a surgical operation?
- Is the device dependent on an energy source (active)?
- Does the device deliver energy, including ionizing radiation, to the body?
- Does the device deliver or remove substances to the body in a potentially hazardous way?
- What is the current level of knowledge regarding the technology and materials incorporated in the medical device
- How much is known about the medical condition the device is intended to treat or diagnose?
- What is the degree of user or patient intervention?
- Does the device control treatment of a patient's condition through a closed-loop system?
- Are the test methods used for assessing the device well known and standardized? Are there international consensus standards available for test methods?
- Is the device intended for use by professional health care providers only, or will it be used by the general public after being prescribed by a physician or after direct purchase from a retail outlet?
- Does the device incorporate tissues or materials of human or animal origin, living or non-living?
- Does the device incorporate an ancillary medicinal/drug product?
- Does the device have a new intended purpose?
- Is there a body of post-market experience with devices of the same type? Are international product safety standards available for the device type?

Flow charts demonstrating how these parameters might be used to classify specific devices are included below.

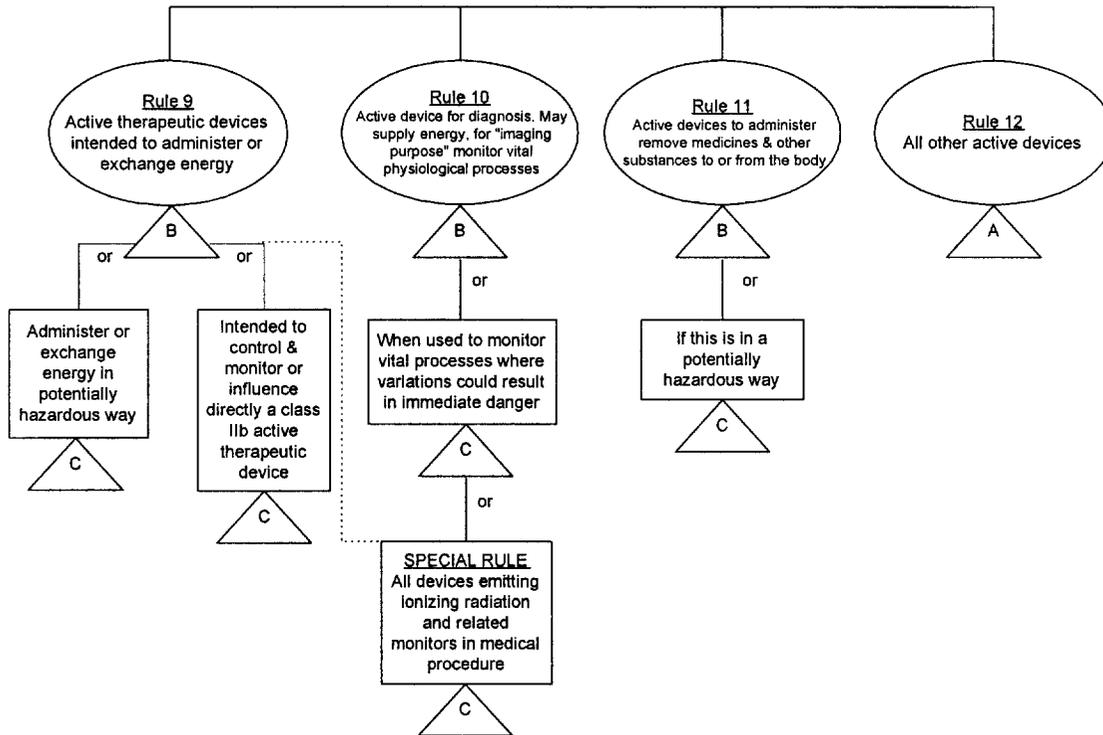
Figure 3: Decision Trees to demonstrate how these parameters might be used to classify specific devices.



INVASIVE DEVICES



ACTIVE DEVICES



SPECIAL RULES

