GHTF Study Group 1 Guidance: *Medical Devices Classification*

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Michael B. Gropp
Guidant Corporation
EUCOMED Special Representative
AdvaMed Special Representative

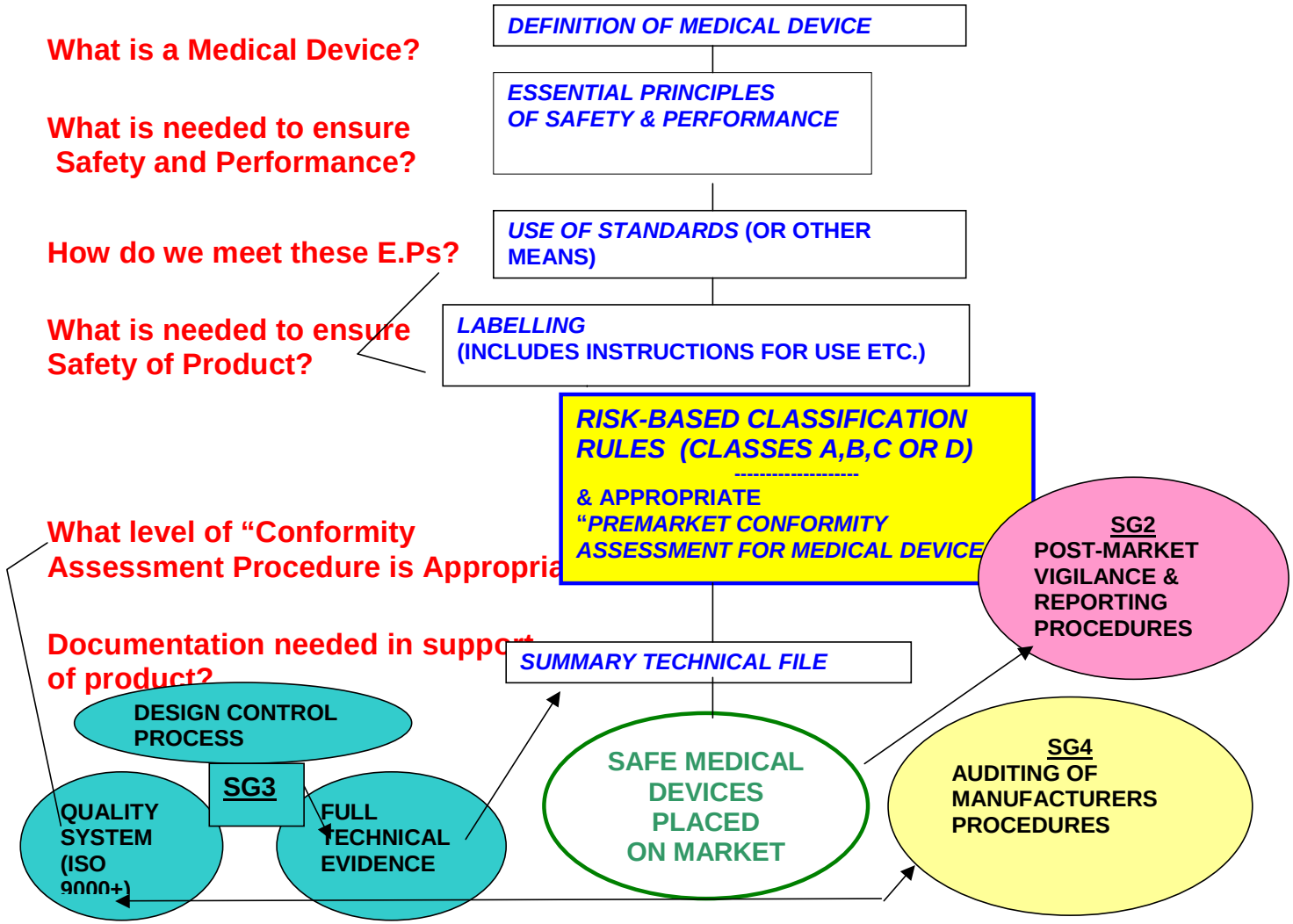
AdvaMed
Advanced Medical Technology Association

EUCOMED

Medical Device Classification

- **Presentation overview:**
  - **Overview of work programme of SG-1**
  - **Overview of device classification draft guidance**
    - **Definitions**
    - **General principles**
    - **Recommendations**
    - **Reclassification**
    - **Proposed classification rules**
    - **Link with conformity assessment**

SCOPE OF GHTF-SG1 PREMARKET TECHNICAL REQUIREMENTS



Medical Device Classification

- **Reference document:**
  - **GHTF *Medical Devices Classification*, Working draft, SG1/N15R14; 10 January 2001**
    - **Accessible on GHTF website:** http://www.ghtf.org/sg1/inventorysg1/sg1-n15r14.doc
  - **Amended 3 August; SG1/N015R15 (not yet published)**

Medical Device Classification

- **Why classify medical devices?**

Medical Device Classification

- **Why classify medical devices?**
  - **Recognition of differing degrees of inherent risk**
  - **Establish conformity assessment requirements**
  - **Establish conformity assessment process options**
  - **Regulatory controls proportional to risk**

Medical Device Classification

- **Why harmonise the classification of medical devices?**

Medical Device Classification

- **Why harmonise the classification of medical devices?**
  - **Consistent, predictable regulatory approach in trading partners**
  - **Facilitate discussions amongst regulators when dealing with suspected device problems**

Medical Device Classification

- **Why harmonise the classification of medical devices?**
  - **"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 the global context unless other or additional, conformity assessment procedures are carried out."**

Essential Principles of Safety and Performance

- **Document overview:**
  - **"This document has been developed to encourage and support global convergence of regulatory systems and the means of achievement. It is intended for use by medical devices regulators, Conformity Assessment Bodies and industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. The document will be of value to countries developing or amending regulations. ……"**

Essential Principles of Safety and Performance

- **Document overview - Purpose:**
  - **“The purpose of this document is to allow a manufacturer to allocate its medical device to an appropriate risk class using a set of harmonized rules.**
  - **Subsequently, such classification will prescribe how the manufacturer will demonstrate that its device complies with the *Essential Principles* ….. , *Labelling* …. and any other relevant controls, should it be required or requested so to do by a Regulatory Authority, Conformity Assessment Body, user or third party.”**

Essential Principles of Safety and Performance

- **Document overview - Definitions:**
  - **"Active medical device: Any medical device operation of which 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."**

Essential Principles of Safety and Performance

- **Document overview - Definitions:**
  - **"Active therapeutical device: Any 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."**

Essential Principles of Safety and Performance

- **Document overview - Definitions:**
  - **"Active device for diagnosis: Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities."**

Essential Principles of Safety and Performance

- **Document overview - Definitions:**
  - **"Central circulatory system: …. means the major internal blood vessels including the following:**
    - ***arteria pulmonales, aorta ascendens, arteria coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteria cerebrales, truncus branchicephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior*"**

Essential Principles of Safety and Performance

- **Document overview - Definitions:**
  - **"Central nervous system: …. means brain, meninges and spinal cord."**

Essential Principles of Safety and Performance

- **Document overview - Definitions:**
  - **"Duration of use:**
    - **Transient: Normally intended for continuous use for less than 60 minutes.**
    - **Short term: Normally intended for continuous use for not more than 30 days.**
    - **Long term: Normally intended for continuous use for more than 30 days."**

Essential Principles of Safety and Performance

- **Document overview - Definitions:**
  - **"Invasive devices:**
    - **Invasive device: A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.**
    - **Body orifice: Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma."**
  -

Essential Principles of Safety and Performance

- **Document overview - Definitions:**
  - **"Invasive devices**
    - **Surgically invasive device: 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.**
    - **Devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices."**

Essential Principles of Safety and Performance

- **Document overview - Definitions:**
  - **"Implantable device: Any device which is intended:**
    - **to be totally introduced into the human body or**
    - **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."**

Essential Principles of Safety and Performance

- **Document overview - Definitions:**
  - **"Harm: Physical injury or damage to the health of people.**
  -
  - **Hazard: Potential source of harm.**
  -
  - **Immediate Danger: A situation where therapy is required as soon as possible after the abnormal condition is diagnosed in order to prevent serious harm to the patient."**

Essential Principles of Safety and Performance

- **Document overview - Definitions:**
  - **"Life Supporting: Maintains the life of a patient over a short period of time.**
  - **Life Sustaining: Maintains the life of a patient over a long period of time.**
  - **Potentially Hazardous Manner: The potential of the device, when used as intended, to harm the patient due, for example, to the lack of direct oversight of the patient by a clinician or the high risk associated with the particular application of the device or the type of technology involved."**

Essential Principles of Safety and Performance

- **Document overview - Definitions:**
  - **"Reusable surgical instrument: Instrument intended for surgical use by cutting, drilling, sawing, scratching, scrap-ing, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be used after appropriate procedures have been carried out.**
  - **Risk: Combination of the probability of occurrence of harm and the severity of that harm."**

Essential Principles of Safety and Performance

- **Document overview – General principles:**
  - **"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.**

Essential Principles of Safety and Performance

- **Document overview – General principles:**
  - **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."**

Medical Device Classification

- **Document overview – Recommendations:**
  - **"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. Based on experience of GHTF Founding Members, this is sufficient to accommodate all medical devices and allows an efficient and graduated system of conformity assessment controls;"**

Medical Device Classification

- **Document overview – Recommendations:**
  - **"the determination of class should be based on a set of rules derived from those features of devices that create risk;**
  - **the set of rules should be sufficiently clear that manufacturers may readily identify the class of their medical devices, subject, when appropriate, to confirmation by the Regulatory Authority;**

Medical Device Classification

- **Document overview – Recommendations:**
  - **"the rules should be capable of accommodating future technological developments;**
  - **any exceptions to the classification rules introduced by a Regulatory Authority to reflect and implement national health policy within its own jurisdiction should be minimized and eliminated in the long term."**

Medical Device Classification

- **Document overview – Recommendations:**
  - **"Where a medical device has features that place it into more than one class, conformity assessment should be based on the highest class indicated.**
  - **Notwithstanding the risk class of a particular medical device, all devices should conform to the applicable *Essential Principles* of Safety and Performance of Medical Devices and for *Labelling for Medical Devices*."**

Medical Device Classification

- **Document overview – Recommendations:**
  - **"Each Regulatory Authority may assign names or numbers to the risk classes, based on local preference. At this time, regulatory controls assigned to each Class by different Regulatory Authorities have yet to be harmonized and vary Guidance on the link between risk class and conformity assessment will be the subject of a future GHTF document."**

Medical Device Classification

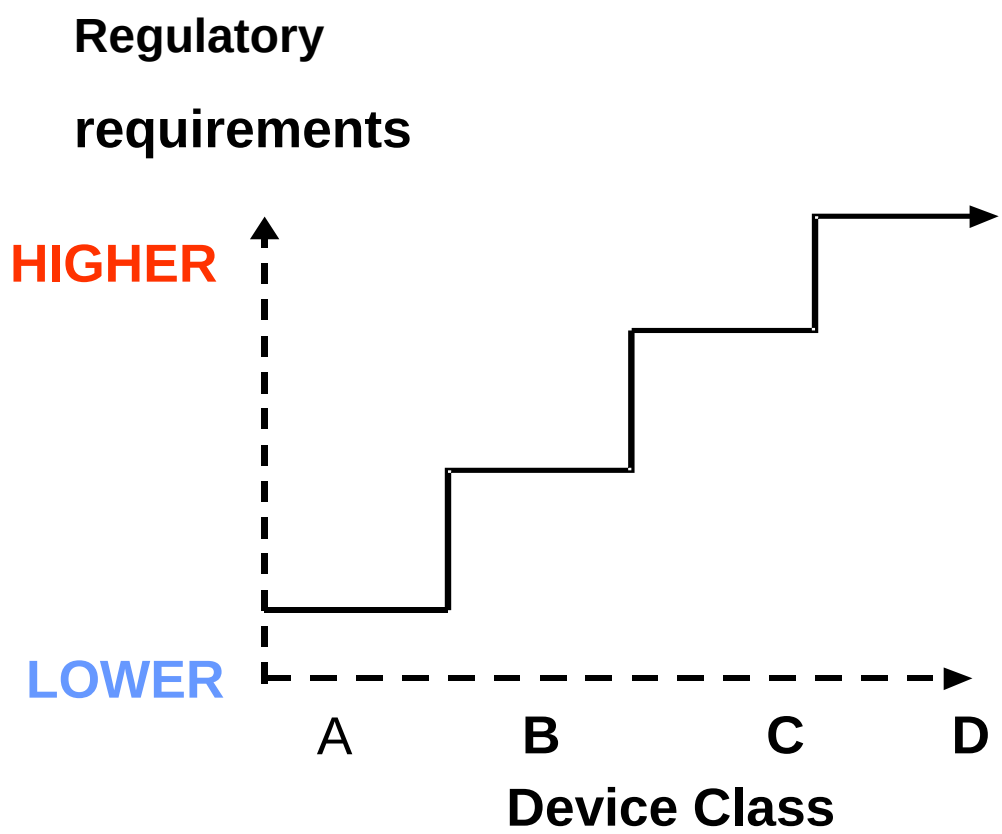
- **Document overview – Recommendations:**
- **Subsequent reclassification:**
  - **“The recognized level of risk may change based on post-market experience or technological improvements to the device. This may lead to a need for reclassification.**
  - **Regulatory Authorities are encouraged to include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

Medical Device Classification

- **Document overview – Recommendations:**
  - **Proposed general classification system for medical devices**

Class	Risk Level	Device examples (illustrative only)
A	Low	Simple surgical instruments/ tongue depressors
B	Low-moderate	Hypodermic needles/suction equipment
C	High-moderate	Lung ventilator/orthopaedic implants
D	High	Heart valve/implantable defibrillator

Medical Device Classification



Medical Device Classification

- **Document overview – Recommendations:**
  - **“Conceptual illustration of increasing levels of regulatory requirements as the device risk class increases. These regulatory controls may include, for example …..**

Medical Device Classification

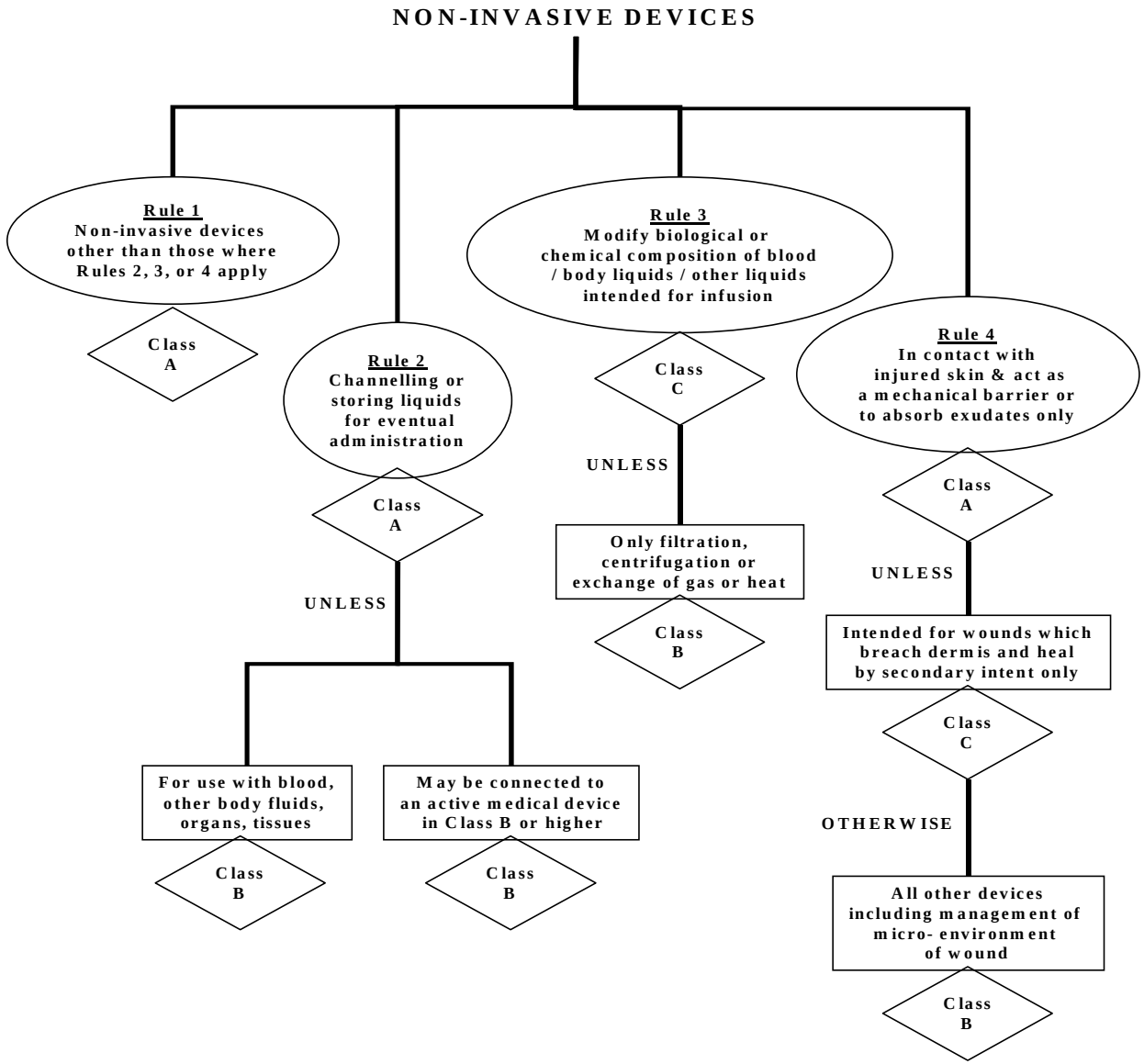
- **Document overview – Recommendations:**
  - **"operation of a quality system (recommended for all devices);**
  - **documentation of clinical evidence to support the manufacturer's claims;**
  - **technical data;**
  - **product testing using in-house or independent resources;**
  - **the need for and frequency of independent external audit of the manufacturer's quality system; and**
  - **independent external review of the manufacturer's technical data."**

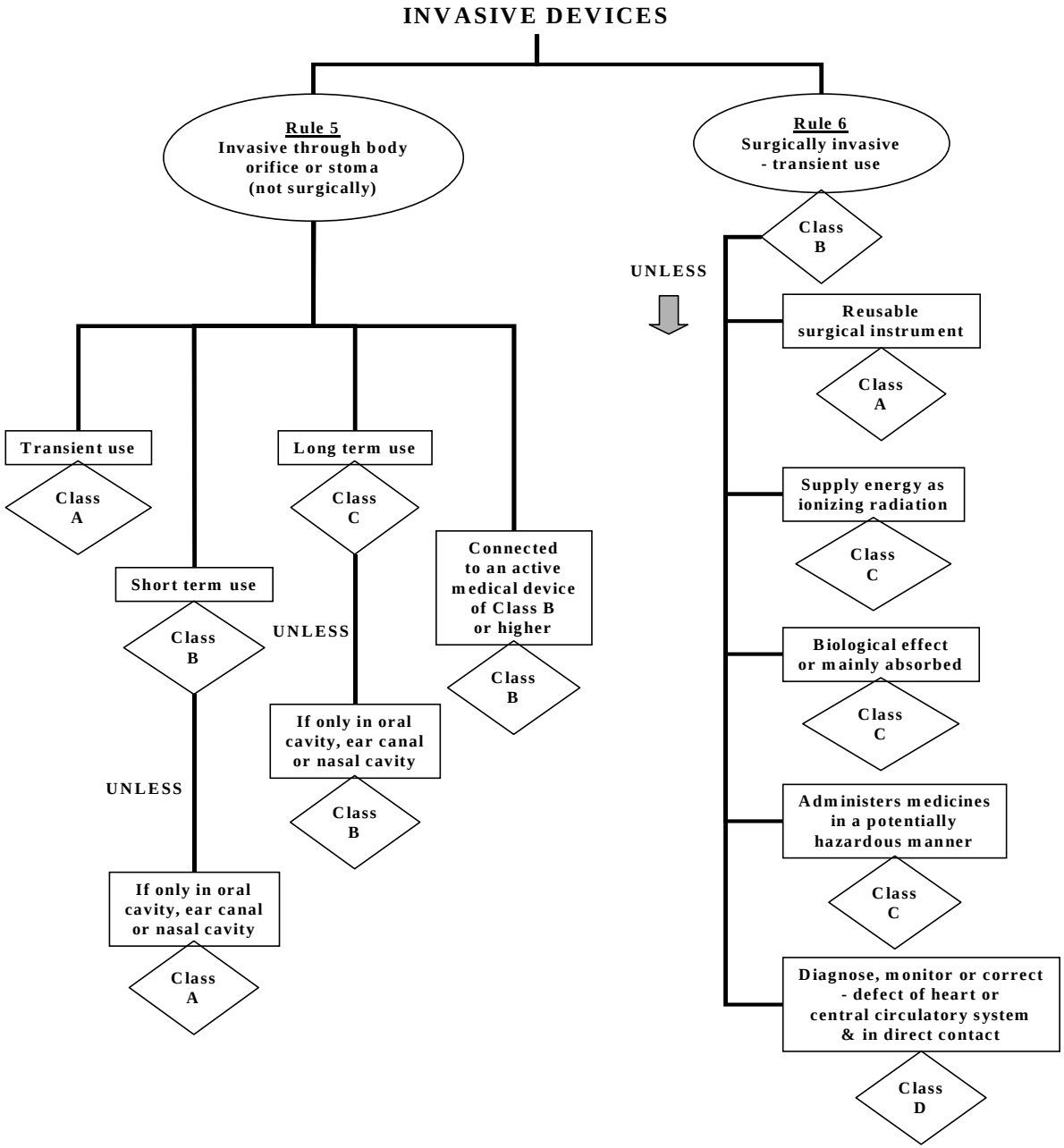
Medical Device Classification

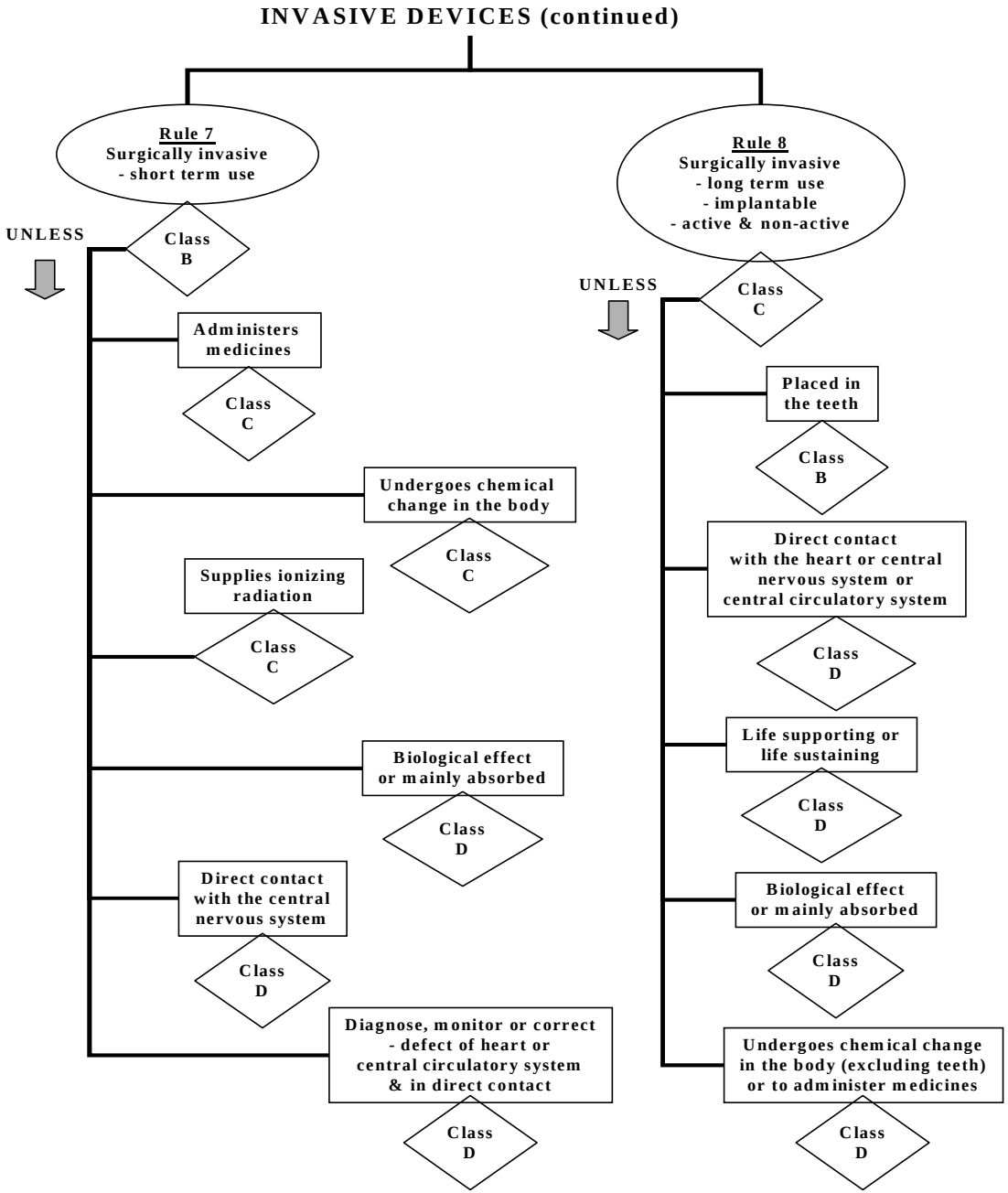
- **Document overview – Determination of device class:**
  - **Determine whether product is a “medical device”**
  - **Determine intended purpose(s) of device**
  - **Consider all of the classification rules**
    - **where a medical device has features that place it into more than one class, conformity assessment should be based on the highest class indicated**
  - **Determine that the device is not subject to special national rules**

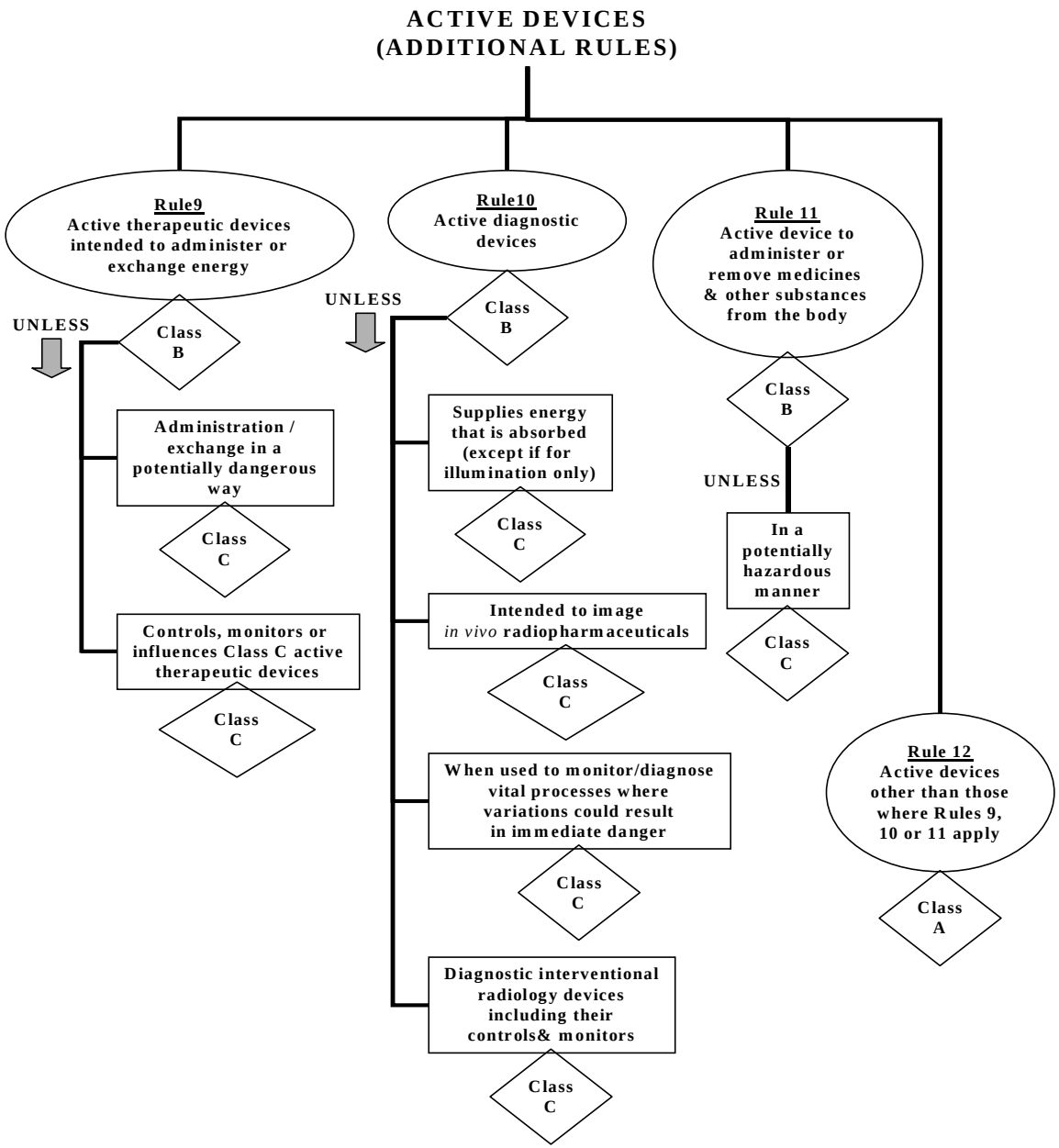
Medical Device Classification

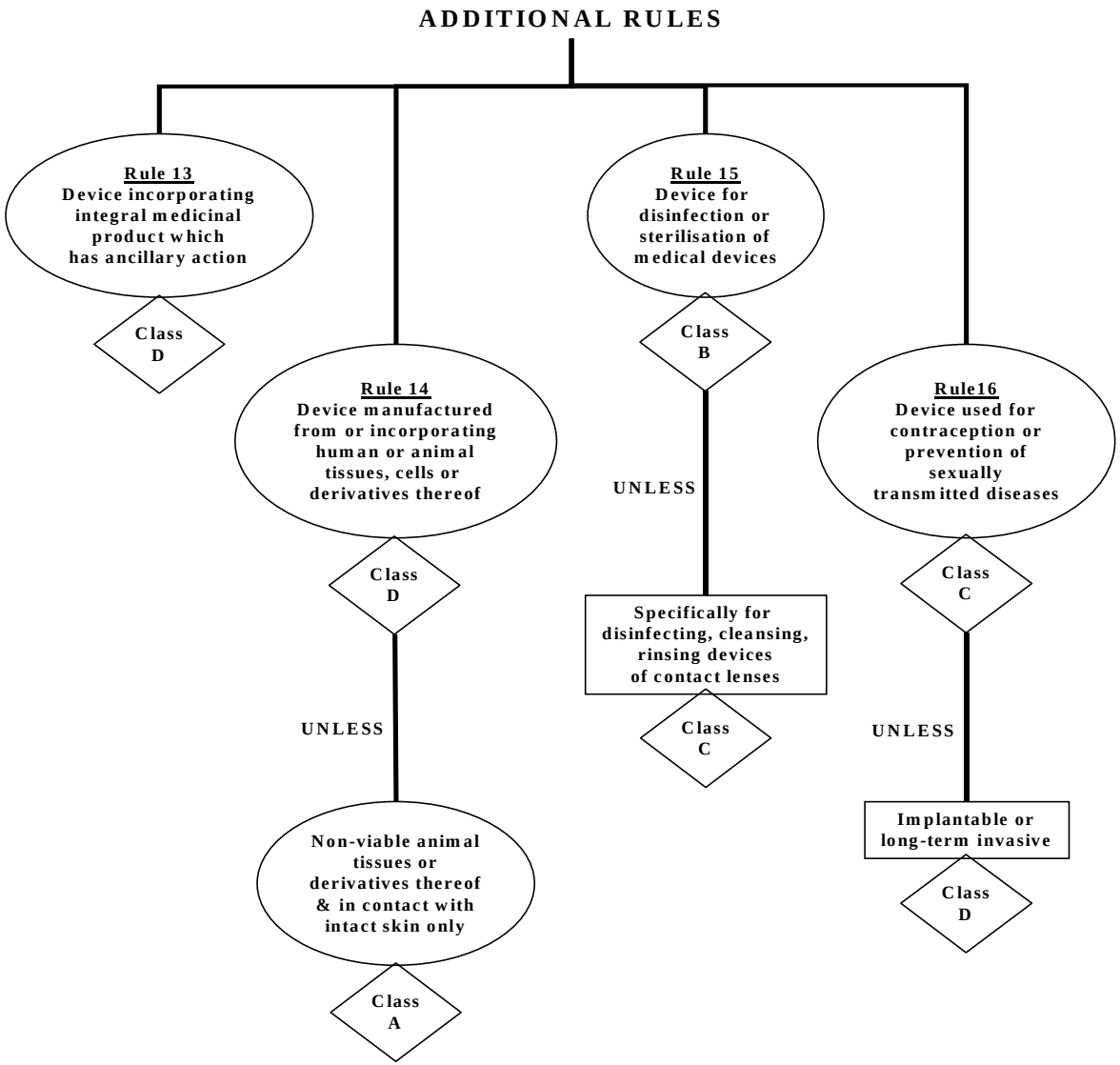
- **Document overview – Classification rules:**
  - **16 rules**
    - **Non-invasive devices**
    - **Invasive devices**
    - **Active devices**
    - **Additional (special) rules**
      - **Specific public health considerations**
  - **Rules illustrated by decision trees**
    - **Rules take precedence over decision trees**


NON-INVASIVE DEVICES
Rule 1
Non-invasive devices other than those where Rules 2, 3, or 4 apply
Class A
Rule 2
Channelling or storing liquids for eventual administration
Class A
UNLESS
For use with blood, other body fluids, organs, tissues
Class B
May be connected to an active medical device in Class B or higher
Class B
Rule 3
Modify biological or chemical composition of blood / body liquids / other liquids intended for infusion
Class C
UNLESS
Only filtration, centrifugation or exchange of gas or heat
Class B
Rule 4
In contact with injured skin & act as a mechanical barrier or to absorb exudates only
Class A
UNLESS
Intended for wounds which breach dermis and heal by secondary intent only
Class C
OTHERWISE
All other devices including management of micro- environment of wound
Class B


INVASIVE DEVICES
Rule 5
Invasive through body orifice or stoma (not surgically)
Rule 6
Surgically invasive - transient use
Transient use
Class A
Short term use
Class B
UNLESS
If only in oral cavity, ear canal or nasal cavity
Class A
Long term use
Class C
UNLESS
If only in oral cavity, ear canal or nasal cavity
Class B
Connected to an active medical device of Class B or higher
Class B
Class B
UNLESS
Reusable surgical instrument
Class A
Supply energy as ionizing radiation
Class C
Biological effect or mainly absorbed
Class C
Administers medicines in a potentially hazardous manner
Class C
Diagnose, monitor or correct - defect of heart or central circulatory system & in direct contact
Class D


INVASIVE DEVICES (continued)
Rule 7
Surgically invasive
- short term use
UNLESS
Class B
Administers medicines
Class C
Undergoes chemical change in the body
Class C
Supplies ionizing radiation
Class C
Biological effect or mainly absorbed
Class D
Direct contact with the central nervous system
Class D
Diagnose, monitor or correct - defect of heart or central circulatory system & in direct contact
Class D
Rule 8
Surgically invasive
- long term use
- implantable
- active & non-active
UNLESS
Class C
Placed in the teeth
Class B
Direct contact with the heart or central nervous system or central circulatory system
Class D
Life supporting or life sustaining
Class D
Biological effect or mainly absorbed
Class D
Undergoes chemical change in the body (excluding teeth) or to administer medicines
Class D


ACTIVE DEVICES
(ADDITIONAL RULES)
Rule9
Active therapeutic devices intended to administer or exchange energy
UNLESS
Class B
Administration / exchange in a potentially dangerous way
Class C
Controls, monitors or influences Class C active therapeutic devices
Class C
Rule10
Active diagnostic devices
UNLESS
Class B
Supplies energy that is absorbed (except if for illumination only)
Class C
Intended to image in vivo radiopharmaceuticals
Class C
When used to monitor/diagnose vital processes where variations could result in immediate danger
Class C
Diagnostic interventional radiology devices including their controls& monitors
Class C
Rule 11
Active device to administer or remove medicines & other substances from the body
Class B
UNLESS
In a potentially hazardous manner
Class C
Rule 12
Active devices other than those where Rules 9, 10 or 11 apply
Class A


ADDITIONAL RULES
Rule 13
Device incorporating integral medicinal product which has ancillary action
Class D
Rule 14
Device manufactured from or incorporating human or animal tissues, cells or derivatives thereof
Class D
UNLESS
Non-viable animal tissues or derivatives thereof & in contact with intact skin only
Class A
Rule 15
Device for disinfection or sterilisation of medical devices
Class B
UNLESS
Specifically for disinfecting, cleansing, rinsing devices of contact lenses
Class C
Rule16
Device used for contraception or prevention of sexually transmitted diseases
Class C
UNLESS
Implantable or long-term invasive
Class D

Medical Device Classification