unless they are intended to administer medicines, in which case they are in Class C;	**NOTE**: the term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine 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 C;	Example: surgical adhesive.
unless they are intended to supply energy in the form or ionizing radiation, in which case they are in Class C;	Example: 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 D;	Example: 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 D;	Example: 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 D.	Examples: cardiovascular catheters; temporary pacemaker leads; carotid artery shunts.
8. All implantable devices, and long-term surgically invasive devices, are in Class C,	Most of the devices covered by this rule are implants used in the orthopaedic, dental, ophthalmic and cardiovascular fields. Example: maxilla-facial implants; prosthetic joint replacements; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibular 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 B;	Examples: bridges; crowns; dental filling materials.
unless they are intended to be used in	Examples: prosthetic heart valves; spinal

direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D;	and vascular stents.
unless they are intended to be life supporting or life sustaining, in which case they are in Class D;	
unless they are intended to be active implantable medical devices, in which case they are Class D;	Example: 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 D;	Example: 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 medicines, in which case they are in Class D;	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 D.	**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 D.	
➢ ***ACTIVE DEVICES – ADDITIONAL RULES***	
9. All active therapeutic devices intended to administer or exchange energy are in Class B,	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.
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 C.	Examples: 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.
All active devices intended to control or monitor the performance of active	Examples: external feedback systems for active therapeutic devices.

therapeutic devices in Class C, or intended directly to influence the performance of such devices, are in Class C.	
10. Active devices intended for diagnosis are in Class B:	Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals, interventional radiology and diagnostic radiology.
- 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 A), 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 C.	Example: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors. Example: ultrasound equipment for use in interventional cardiac procedures.
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 C.	Example: diagnostic X-ray source; devices for the control, monitoring or influencing of the emission of ionizing radiation.
11. All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class B,	Such devices are mostly drug delivery systems, or anaesthesia equipment. Examples: feeding pumps; jet injectors.
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	Examples: infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers.

mode of application, in which case they are in Class C.	
12. All other active devices are in Class A.	Examples: examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.
➢ ***ADDITIONAL RULES***	
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 D.	These devices cover combination devices that incorporate medicinal substances in a secondary role. Examples: antibiotic bone cements; heparin-coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound.
14. All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are Class D,	**NOTE**: In some jurisdictions such products: - are considered to be outside the scope of the medical device definition; - may be subject to different controls. It is likely the regulations controlling these devices will be the subject of future harmonization efforts. Examples: porcine heart valves; catgut sutures..
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 A.	Examples: leather components of orthopaedic appliances.
15. All devices intended specifically to be used for disinfecting or sterilising medical devices are in Class B,	Examples: disinfectants intended to be used with medical devices; washer disinfectors. **NOTE:** This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action e.g. washing machines.
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 C.	Examples: contact lens solutions. **NOTE**: In some jurisdictions solutions for use with contact lenses: - are considered to be outside the scope of the medical devices definition; - may be subject to different controls.
16. All devices used for contraception or	Examples: condoms; contraceptive

the prevention of the transmission of sexually transmitted diseases are in Class C,	diaphragms.
unless they are implantable or long-term invasive devices, in which case they are in Class D.	Example: intrauterine contraceptive device.

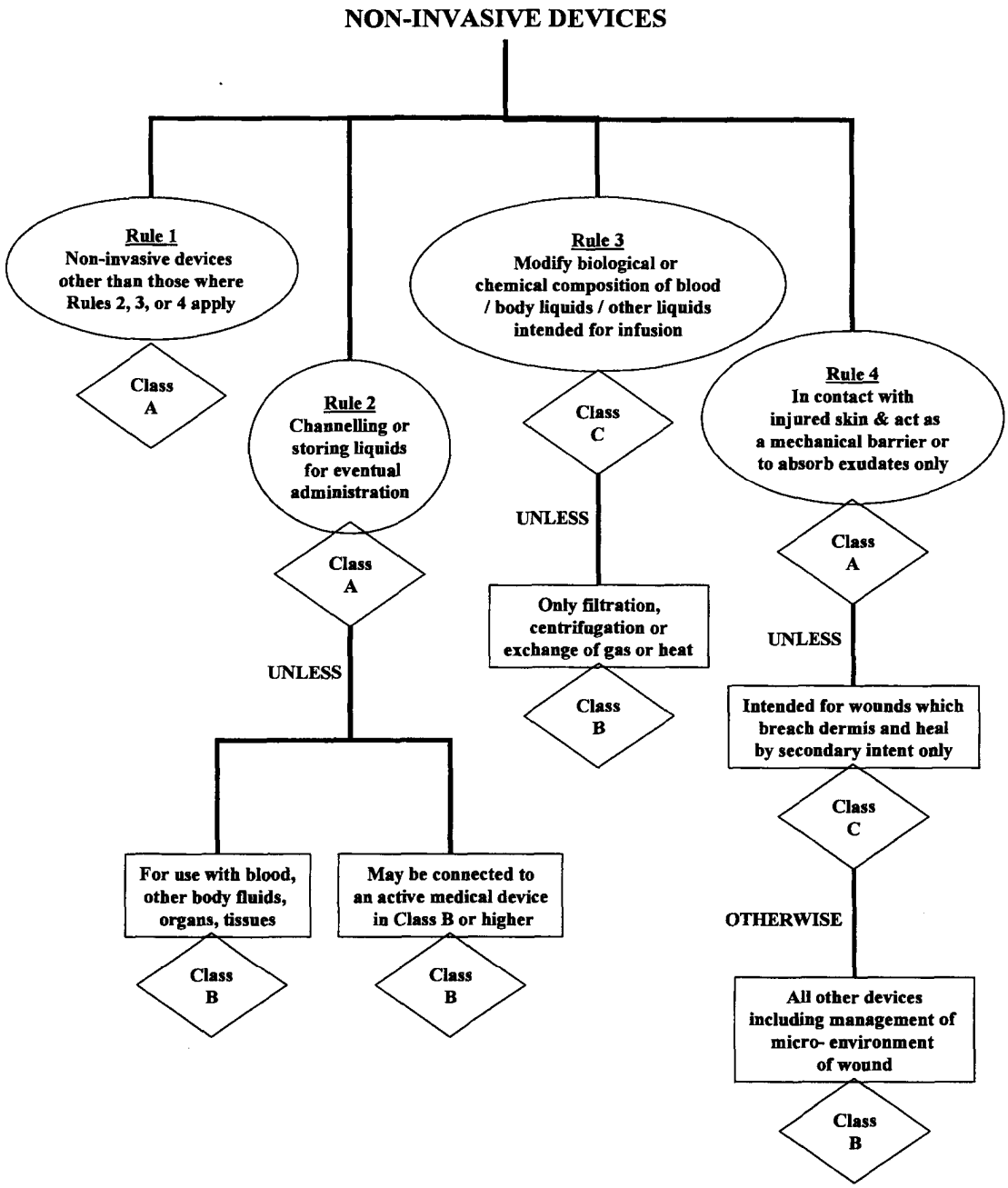
Decision trees illustrating how these rules should be used to classify specific devices are shown below.

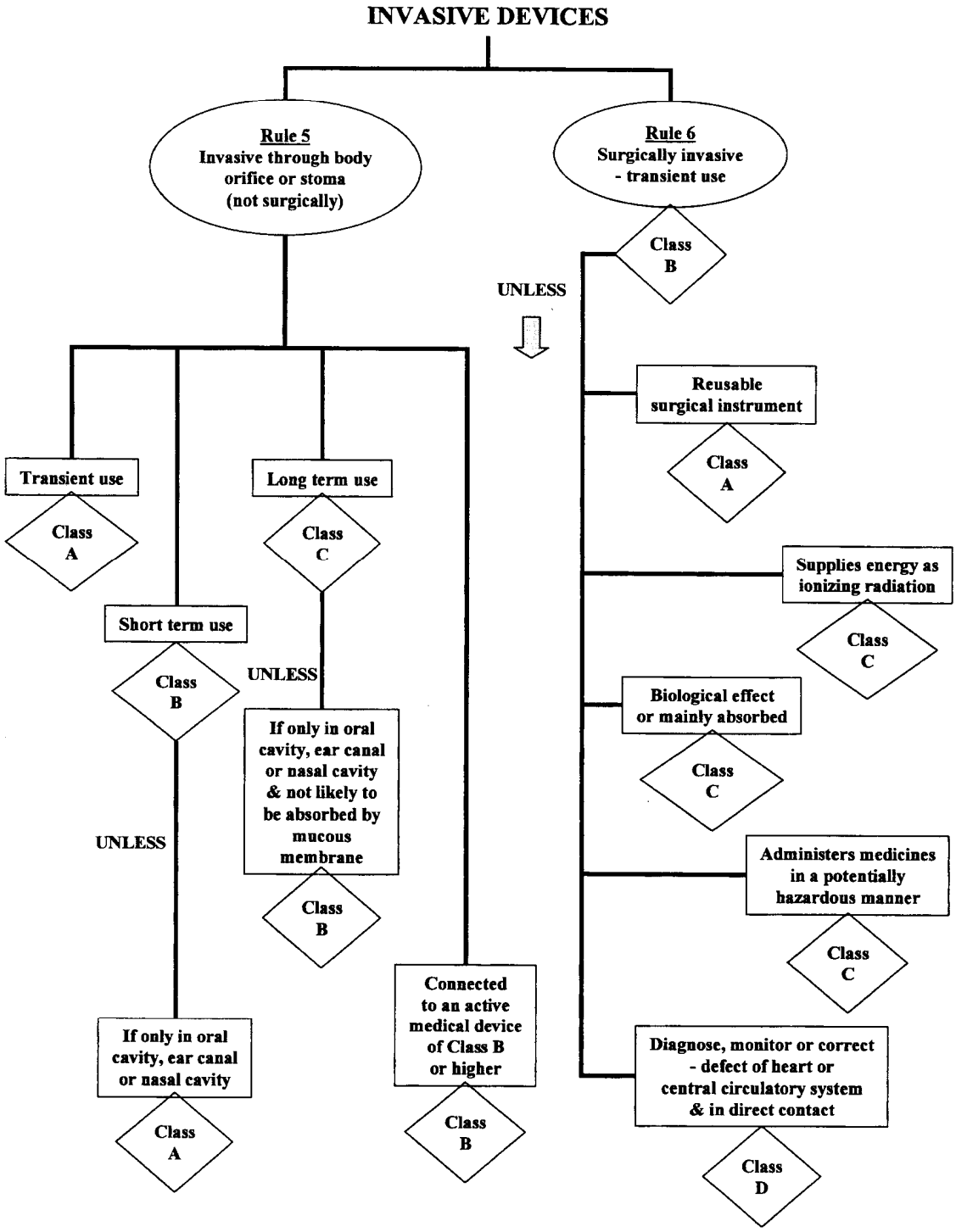
NOTE: these diagrams are for illustrative purposes only and the determination of risk class for a particular device should be made by referring to the rules themselves and not the decision trees.

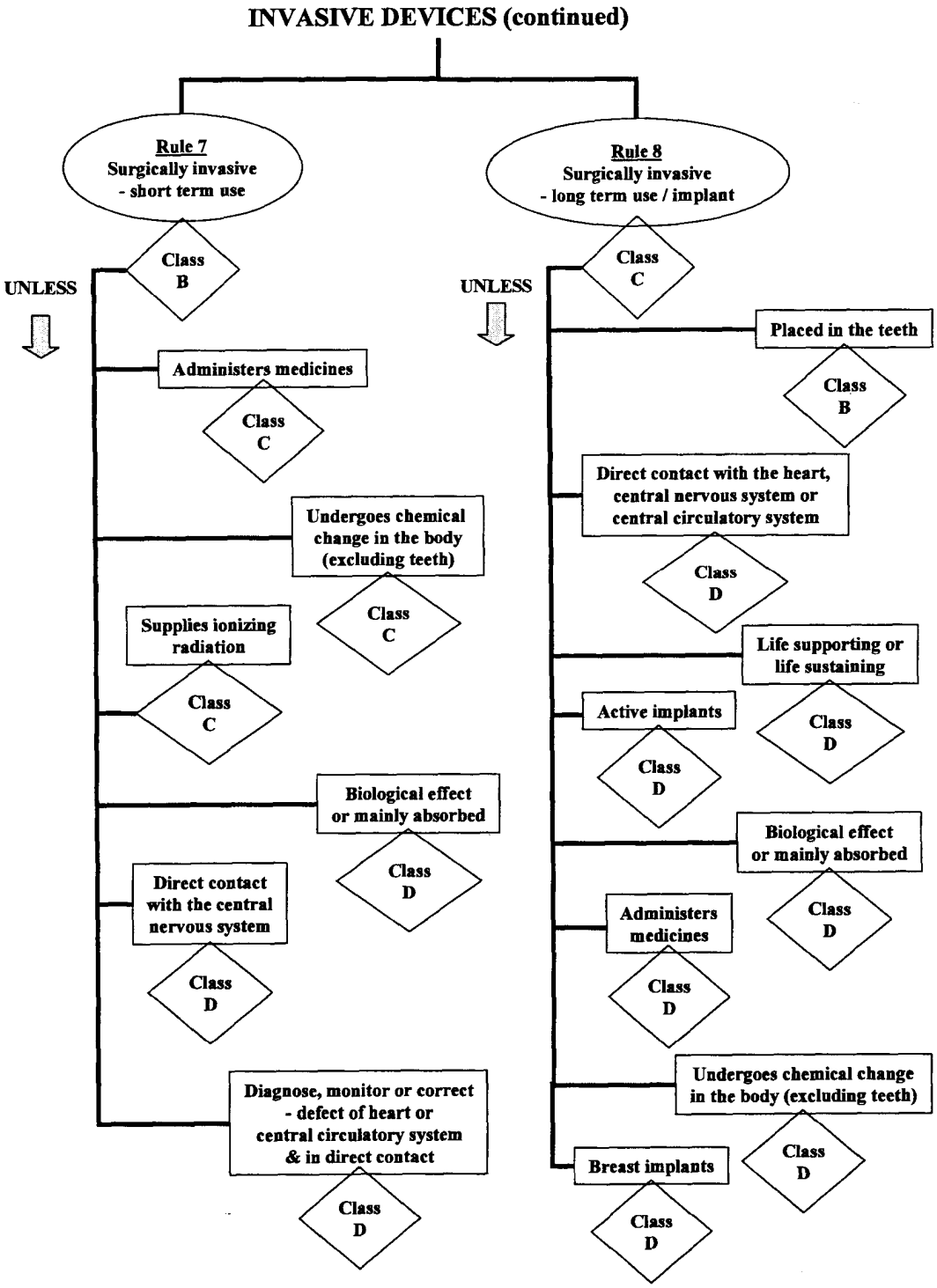
NOTE: where a medical device has features that place it into more than one class, conformity assessment should be based on the highest class indicated.

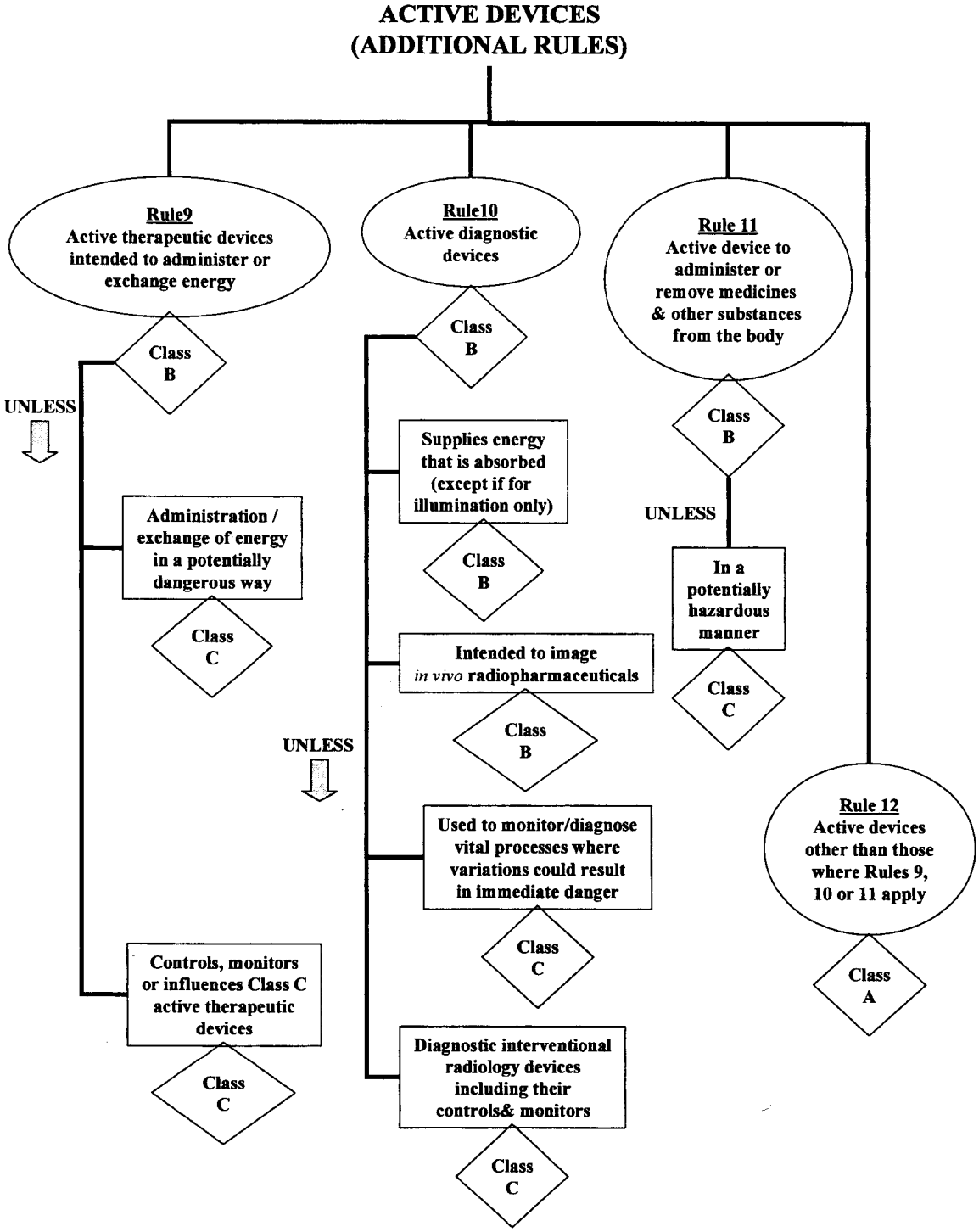
-

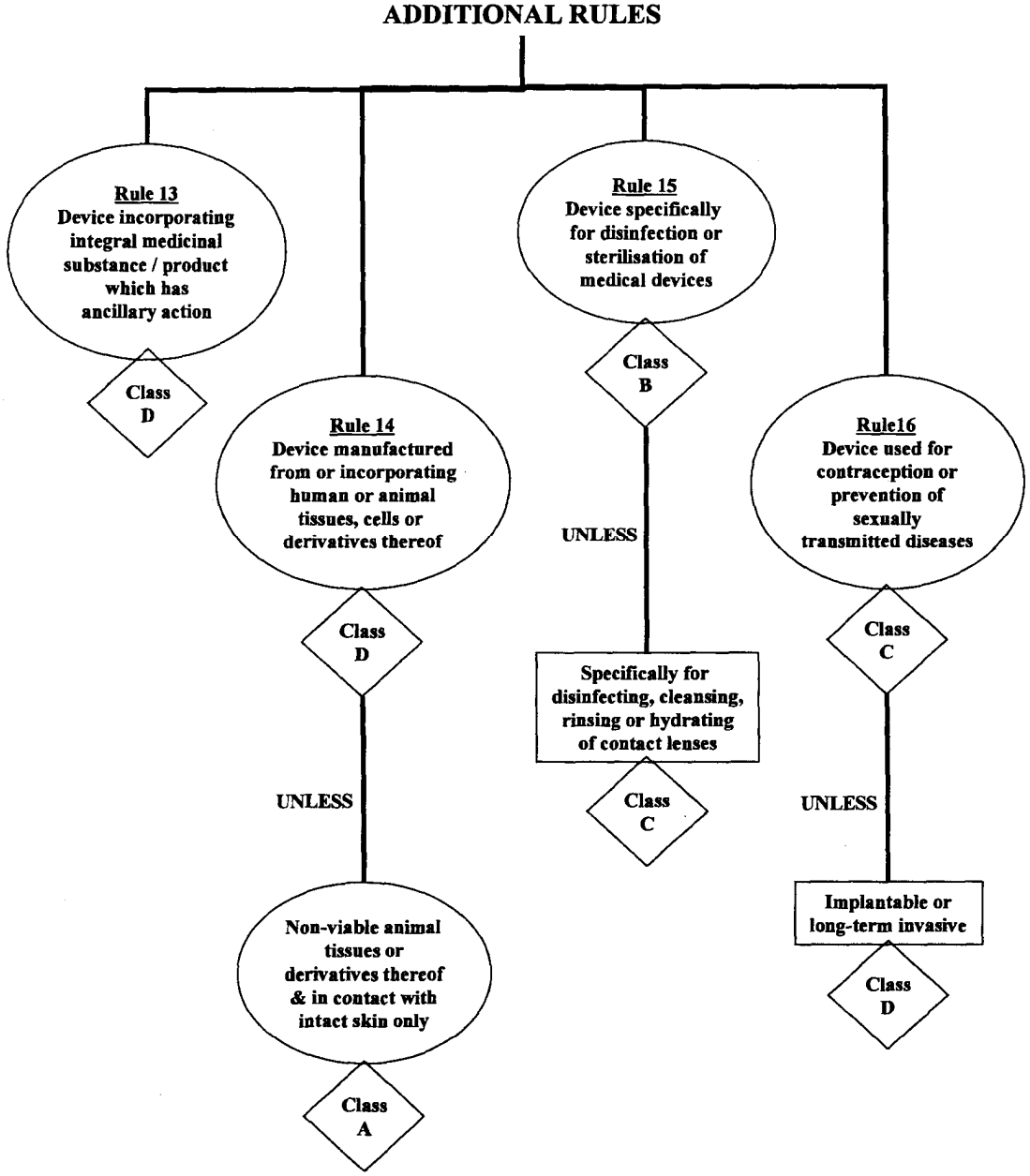
Figure 3: Decision Trees to demonstrate how these rules should be used to classify specific devices.




INVASIVE DEVICES
Rule 5
Invasive through body orifice or stoma (not surgically)
Rule 6
Surgically invasive - transient use
Class B
UNLESS
Transient use
Class A
Long term use
Class C
Short term use
Class B
UNLESS
If only in oral cavity, ear canal or nasal cavity & not likely to be absorbed by mucous membrane
Class B
UNLESS
If only in oral cavity, ear canal or nasal cavity
Class A
Connected to an active medical device of Class B or higher
Class B
Reusable surgical instrument
Class A
Supplies 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
Class
B
UNLESS
Administers medicines
Class
C
Undergoes chemical change in the body (excluding teeth)
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 / implant
Class
C
UNLESS
Placed in the teeth
Class
B
Direct contact with the heart, central nervous system or central circulatory system
Class
D
Life supporting or life sustaining
Class
D
Active implants
Class
D
Biological effect or mainly absorbed
Class
D
Administers medicines
Class
D
Undergoes chemical change in the body (excluding teeth)
Class
D
Breast implants
Class
D


ACTIVE DEVICES
(ADDITIONAL RULES)
Rule9
Active therapeutic devices intended to administer or exchange energy
Class B
UNLESS
Administration / exchange of energy in a potentially dangerous way
Class C
Controls, monitors or influences Class C active therapeutic devices
Class C
Rule10
Active diagnostic devices
Class B
Supplies energy that is absorbed (except if for illumination only)
Class B
Intended to image in vivo radiopharmaceuticals
Class B
UNLESS
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 substance / 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 specifically for disinfection or sterilisation of medical devices
Class B
UNLESS
Specifically for disinfecting, cleansing, rinsing or hydrating 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