

Classification Rules for Medical Devices^a

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.

RULE	ILLUSTRATIVE EXAMPLES OF DEVICES THAT MAY CONFORM WITH A RULE
➤ <i>NON-INVASIVE DEVICES</i>	
1. All non-invasive devices are in Class I, unless Rule 2, 3 or 4 applies.	<p>These devices either do not touch the patient or contact intact skin only.</p> <p><u>Examples:</u> urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.</p> <p>NOTE: Non-invasive devices that are <u>indirectly</u> 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.</p>
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 I,	<p>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).</p> <p><u>Examples:</u> administration sets for gravity infusion; syringes without needles.</p>

^a These have been adopted from Global Harmonization Task Force. Principles of Medical Devices Classification. Proposed Document SG1/N015R22. <http://www.ghtf.org> accessed on 30 October 2004. Classes I, II, III and IV are referred to respectively as Classes A, B, C and D in SG1/N015R22.

<p>unless they may be connected to an active medical device in Class II or a higher class, in which case they are Class II;</p>	<p><u>Examples:</u> syringes and administration sets for infusion pumps; anaesthesia breathing circuits.</p> <p>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 <i>vice versa</i>.</p>
<p>unless they are intended for use of storing or channeling blood or other body liquids or for storing organs, parts of organs or body tissues, in which case they are Class II.</p>	<p><u>Examples:</u> tubes used for blood transfusion.</p>
<p>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,</p>	<p>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.</p> <p><u>Examples:</u> haemodialyzers; devices to remove white blood cells from whole blood.</p> <p>NOTE: for the purpose of this part of the rule, ‘modification’ does not include simple, mechanical filtration or centrifuging which are covered below.</p>
<p>unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class II.</p>	<p><u>Examples:</u> devices to warm or cool blood; devices to remove carbon dioxide; particulate filters in an extracorporeal circulation system.</p>
<p>4. All non-invasive devices which come into contact with injured skin:</p>	<p>Devices covered by this rule are extremely claim sensitive.</p>
<p>- are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;</p>	<p><u>Examples:</u> simple wound dressings; cotton wool.</p>
<p>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 III.</p>	<p>Devices used to treat wounds where the subcutaneous tissue is at 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 III.</p> <p><u>Examples:</u> dressings for chronic ulcerated wounds; dressings for severe burns.</p>
<p>- are in Class II in all other cases, including devices principally intended to manage the microenvironment of a wound.</p>	<p><u>Examples:</u> non-medicated impregnated gauze dressings.</p>

➤ **INVASIVE DEVICES**

<p>5. All invasive devices with respect to body orifices (other than those which are surgically invasive) and which:</p> <p>a) are not intended for connection to an active medical device or</p> <p>b) are intended for connection to a Class I medical device</p>	<p>Such devices are invasive in body orifices and are not surgically invasive. Devices tend to be 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.</p>
<p>- are in Class I if they are intended for transient use;</p>	<p><u>Examples:</u> dental impression materials; examination gloves; enema devices.</p>
<p>- are in Class II if they are intended for short-term use;</p>	<p><u>Examples:</u> contact lenses, urinary catheters, tracheal tubes.</p>
<p>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 I,</p>	<p><u>Examples:</u> dentures intended to be removed by the patient; dressings for nose bleeds.</p>
<p>- are in Class III if they are intended for long-term use;</p>	<p><u>Example:</u> 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).</p>
<p>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 II.</p>	<p><u>Examples:</u> orthodontic wire, fixed dental prosthesis.</p>
<p>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.</p>	<p><u>Examples:</u> tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips.</p> <p>NOTE: independent of the time for which they are invasive.</p>

<p>6. All surgically invasive devices intended for transient use are in Class II,</p>	<p>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.</p> <p>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 Class I.</p> <p>NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.</p>
<p>unless they are reusable surgical instruments, in which case they are in Class I;</p>	<p><u>Examples:</u> Manually operated surgical drill bits and saws.</p>
<p>unless intended to supply energy in the form of ionizing radiation, in which case they are in Class III;</p>	<p><u>Example:</u> catheter incorporating/ containing sealed radioisotopes.</p>
<p>unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class III;</p>	<p>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.</p>
<p>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 III.</p>	<p><u>Example:</u> insulin pen for self-administration.</p> <p>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.</p>
<p>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.</p>	<p><u>Examples:</u> angioplasty balloon catheters and related guide wires; dedicated disposable cardiovascular surgical instruments.</p>

<p>7. All surgically invasive devices intended for short-term use are in Class II,</p>	<p>Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types.</p> <p><u>Examples:</u> clamps; infusion cannulae; temporary filling materials; non-absorbable skin closure devices; tissue stabilisers used in cardiac surgery.</p> <p>NOTE: includes devices that are used during cardiac surgery but do not monitor or correct a defect.</p> <p>NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.</p>
<p>unless they are intended to administer medicines, in which case they are in Class III;</p>	<p>NOTE: the term ‘administration of medicines’ implies storage and/or influencing the rate/volume of medicine delivered not just channelling.</p>
<p>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;</p>	<p><u>Example:</u> surgical adhesive.</p>
<p>unless they are intended to supply energy in the form of ionizing radiation, in which case they are in Class III;</p>	<p><u>Example:</u> brachytherapy device.</p>
<p>unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class IV;</p>	<p><u>Example:</u> absorbable suture; biological adhesive.</p> <p>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.</p>
<p>unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class IV;</p>	<p><u>Example:</u> neurological catheter.</p>
<p>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 IV.</p>	<p><u>Examples:</u> cardiovascular catheters; temporary pacemaker leads; carotid artery shunts.</p>

<p>8. All implantable devices, and long-term surgically invasive devices, are in Class III,</p>	<p>Most of the devices covered by this rule are implants used in the orthopaedic, dental, ophthalmic and cardiovascular fields.</p> <p><u>Example:</u> maxilla-facial implants; prosthetic joint replacements; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating).</p> <p>NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.</p>
<p>unless they are intended to be placed into the teeth, in which case they are in Class II;</p>	<p><u>Examples:</u> bridges; crowns; dental filling materials.</p>
<p>unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class IV;</p>	<p><u>Examples:</u> prosthetic heart valves; spinal and vascular stents.</p>
<p>unless they are intended to be life supporting or life sustaining, in which case they are in Class IV;</p>	
<p>unless they are intended to be active implantable medical devices, in which case they are Class IV;</p>	<p><u>Example:</u> pacemakers, their electrodes and their leads; implantable defibrillators.</p>
<p>unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class IV;</p>	<p><u>Example:</u> implants claimed to be bioactive.</p> <p>NOTE: hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.</p>
<p>unless they are intended to administer medicines, in which case they are in Class IV;</p>	<p><u>Example:</u> rechargeable non-active drug delivery system.</p>
<p>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.</p>	<p>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.</p>
<p>unless they are breast implants, in which case they are in Class IV.</p>	
<p>➤ ACTIVE DEVICES</p>	
<p>9. All active therapeutical devices intended to administer or exchange energy are in Class II,</p>	<p>Such devices are mostly electrically powered equipment used in surgery; devices for specialised treatment and some stimulators.</p> <p><u>Examples:</u> muscle stimulators; TENS devices; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy.</p>

<p>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.</p>	<p><u>Examples:</u> lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; therapeutic X-ray and other sources of ionizing radiation.</p> <p>NOTE: the term ‘potentially hazardous’ refers to the type of technology involved and the intended application.</p>
<p>All active devices intended to control or monitor the performance of active therapeutical devices in Class III, or intended directly to influence the performance of such devices, are in Class III.</p>	<p><u>Examples:</u> external feedback systems for active therapeutical devices.</p>
<p>10. Active devices intended for diagnosis are in Class II:</p>	<p>Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals, interventional radiology and diagnostic radiology.</p>
<p>- 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</p>	<p><u>Examples:</u> magnetic resonance equipment; diagnostic ultrasound in non-critical applications; evoked response stimulators.</p>
<p>- if they are intended to image <i>in vivo</i> distribution of radiopharmaceuticals, or</p>	<p><u>Example:</u> gamma/nuclear cameras.</p>
<p>- if they are intended to allow direct diagnosis or monitoring of vital physiological processes,</p>	<p><u>Example:</u> electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs.</p>
<p>unless they are specifically intended for:</p> <p>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</p> <p>b) diagnosing in clinical situations where the patient is in immediate danger,</p> <p>in which case they are in Class III.</p>	<p><u>Example:</u> monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors.</p> <p><u>Example:</u> ultrasound equipment for use in interventional cardiac procedures.</p>
<p>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.</p>	<p><u>Example:</u> diagnostic X-ray source; devices for the control, monitoring or influencing of the emission of ionizing radiation.</p>

<p>11. All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class II,</p>	<p>Such devices are mostly drug delivery systems, or anaesthesia equipment. Examples: feeding pumps; jet injectors.</p>
<p>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 of application, in which case they are in Class III.</p>	<p><u>Examples:</u> infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers.</p>
<p>12. All other active devices are in Class I.</p>	<p><u>Examples:</u> examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.</p>
<p>➤ ADDITIONAL RULES</p>	
<p>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.</p>	<p>These devices cover combination devices that incorporate medicinal substances in a secondary role. <u>Examples:</u> antibiotic bone cements; heparin-coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound.</p>
<p>14. All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are Class IV,</p>	<p>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:</p> <ol style="list-style-type: none"> 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 of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissues.
<p>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 I.</p>	<p><u>Examples:</u> leather components of orthopaedic appliances.</p>
<p>15. All devices intended specifically to be used for disinfecting or sterilising medical devices are in Class II,</p>	<p><u>Examples:</u> 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.</p>
<p>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.</p>	<p><u>Examples:</u> contact lens solutions. -</p>

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