

Classifications of Medical Devices

For PL insurance, if there is sale to equipment of medical device class III or more, please report the product you are selling.

Classification is in accordance with the Pharmaceutical Affairs Law of Japan.

Classifications of Medical Devices (1)

Pharmaceutical Affairs Law of Japan.

Classifications of Medical Devices		Examples
Specially controlled medical devices	Class IV	<p>Medical devices that are highly invasive whose malfunction is supposed to threaten the life of the patient.</p> <p>Pacemakers, coronary artery stents, absorbable surgical sutures, mammary prostheses, video image flexible vascular endoscopes, central venous catheters, etc.</p>
	Class III	<p>Medical devices whose malfunction is supposed to cause a major influence on the human body, including:</p> <p>Analzers, such as:</p> <p>(1) self-test diagnostic equipment that is used for a test item that can threaten the life or significantly harm the health of the patient when the equipment indicates an incorrect diagnostic result; and</p> <p>(2) dedicated-use analyzers containing major reaction system, those that are used to measure a test item for which an in vitro diagnostic is required to get authorized.</p> <p>Dialysis machines, head prostheses, radiation therapy equipment, blood vessel stents, biliary stents, extracorporeal shock wave lithotripsy equipment, general-purpose infusion pumps, etc.</p>

Classifications of Medical Devices (2)

Pharmaceutical Affairs Law of Japan.

Classifications of Medical Devices		Examples
Controlled medical devices	Class II	<p>Medical devices with a low possibility of causing a life-threatening danger or critical functional failure, including: Analyzers, such as: (1) self-test diagnostic equipment that is used for a test item other than those that could threaten the life or significantly harm the health of the patient when the equipment indicates an incorrect diagnostic result (and self-test diagnostic equipment with which the diagnostic result does not establish a medically-critical condition or those with which the diagnostic result is tentative and requires another appropriate follow-up examination); and (2) dedicated-use analyzers containing major reaction systems, those that do not have a standard product (except for Class III items). Diagnostic imaging equipment, contrast medium injectors, electronic thermometers, electronic blood pressure gauge, electronic endoscopes, dental alloys, etc.</p>
General medical devices	Class I	<p>Medical devices whose malfunction influence on the human body is supposed to be minor, including: Analyzers of the class other than Class II or III, such as those to be mentioned below. •The following analyzers, however, require the minister’s authorization and their class is determined at the time of such authorization: those that are used for a new test item or new measurement principle, those that will undergo a transition to a self-test device, and those for a dedicated use containing major reaction systems that are used to measure a new test item. In vitro diagnostic devices, steel instruments, dental laboratory equipment, X-ray films, stethoscopes, mercury blood pressure gauge, etc.</p>