Medical Application Guide

According to the medical devices classified as GHTF Classes A to C (Japan Classes I to III), we have the corresponding product series (the 2nd code from the left side of the part number is "M" or "L") intended for use in the medical devices. Therefore, when using our products for the medical devices, please be sure to check the classification based on the GHTF Rules and use the corresponding product series.
On the other hand, we don't have the product series intended for use in (i) all medical devices classified as GHTF Class D (Japan Class IV) and (ii) implantable medical devices (bone-anchored hearing aid, artificial retina system, and external unit which is connected to internal unit which is implanted in a body, etc.). Therefore, please do not incorporate our products into these medical devices. Should you have any questions on this matter, please contact us.

Risk Level		Low → High			
Japan	Classification according to the PMD Act of Japan (based on the GHTF Rules)	**Class I** General Medical Devices (GHTF Class A)	**Class II** Controlled Medical Devices (GHTF Class B)	**Class III** Specially-controlled Medical Devices (GHTF Class C)	**Class IV** Specially-controlled Medical Devices (GHTF Class D)
		Medical devices with extremely low risk to the human body in case of problems	Medical devices with relatively low risk to the human body in case of problems	Medical devices with relatively high risk to the human body in case of problems	Medical devices highly invasive to patients and with life-threatening risk in case of problems
		[Ex.] • In Vitro Diagnostic Devices • Nebulizer • Blood Gas Analyzer • Plethysmographs • Breathing Sensor • AC-powered Operating Table • Surgical Light • Cholesterol Analysis Device • Blood Type Analysis Device, etc.	[Ex.] • Electronic Thermometer • Electronic Blood Pressure Gauge • Electronic Endoscope • Hearing Aid • Electrocardiograph • MRI • Ultrasonic Diagnostic System • Diagnostic Imaging Equipment • X-ray Diagnostic Equipment • Central Monitor • Pulse Oximeter, etc.	[Ex.] • Dialysis Machine • Radiation Therapy Equipment • Infusion Pump • Respirator • Glucose Monitoring System • AED (Automated External Defibrillator) • Skin Laser Scanner • Electric Surgical Unit • Insulin Pump, etc.	[Ex.] • Cardiac Pacemaker • Video Flexible Angioscope • Implantable Infusion Pump • Cardiac Electrosurgical Unit • Inspection Device with Cardiac Catheter • Defibrillator, etc.
U.S.A.	FDA Classification	**Class I** General Controls	**Class II** General Controls and Special Controls		**Class III** General Controls and Premarket Approval
		Medical devices without the possibility of causing serious injury or harm to the patient or user even if there is a defect or malfunction in such medical devices	Medical devices with the possibility of causing injury or harm to the patient or user if there is a defect or malfunction in such medical devices		Medical devices with the possibility of causing serious injury, disability or death to the patient or user if a defect or malfunction occurs in such medical devices
Corresponding TAIYO YUDEN Product Series		**Product Series for Medical Devices classified as GHTF Classes A or B (Japan Classes I or II)** (The 2nd Code from the Left Side of the Part Number: "L")		**Product Series for Medical Devices classified as GHTF Class C (Japan Class III)** (The 2nd Code from the Left Side of the Part Number: "M") (See the Note below.)	N / A

* Note : It is prohibited that our products are used in some medical devices such as implantable medical devices even if such medical devices are classified as GHTF Class C (Japan Class III).