

Medical Devices

Class	Risk Level	Examples for reference
I	Low	Stethoscope, Bandages, Wheelchairs, Walking aid, Compression hosiery
II	Low-moderate	Electrocardiograph (ECG), Transcutaneous electrical neuromuscular stimulator (TENS), Hearing aids, Electronic blood pressure monitor, Urinary catheter
III	Moderate-high	Contact lens care solutions, Diagnostic X-ray machines, Automated external defibrillator, Insulin pen, Prosthetic joint
IV	High	Artificial heart valves, Implantable cardiac pacemakers, Neuro-endoscopes, Breast implant

In Vitro Diagnostic (IVD)

Class	Risk Level	Examples for reference
A	Low	Plain urine cup, Identification kits for cultured microorganism
B	Low-moderate	Urine test strips, Pregnancy test kits
C	Moderate-high	Home use blood glucose meters and their test strips, Screening test for Spina Bifida in foetus, Diagnostic assay for Chlamydia pneumonia
D	High	Tests to detect Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV)