

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Needles	Class Is
Syringes	Class Is
Tubular devices	Class Is
Adapters, connectors, ramps, stopcocks, caps	Class Is
Nutrition and infusion bags and containers, single use	Class Is
Gastrointestinal tubes and sets	Class Is
Gauzes	Class Is
Special Dressing	Class Is
Magnetic Drape	Class Is
Operating room accessories	Class Is
Pneumology instruments for removal of secretions	Class Is
Skin cleansing wipes	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.