

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

<b>Device(s)</b>	<b>Risk Classification</b>
Sterile disinfecting port protector devices	Class IIa
Barrier film	Class IIa
Warming Blankets	Class Is
Self-Adherent Wrap	Class Is
Skin Closures	Class Is
Surgical Drapes	Class Is
Incise drapes	Class Is
Surgical drapes – other	Class Is
Skin staple removers	Class Is
Barrier Film	Class Is
Intravascular protection devices	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	