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

Device(s)	Risk Classification
Single Use Orthopaedic Instruments, Sterile and Non-sterile	Class IIa
Orthopaedic Instruments connected to an Active Device	Class IIa
Reusable Surgical Instruments 'Orthopaedic Instruments'	Class Ir
Reusable Surgical Instruments 'General Surgery Instruments'	Class Ir
Reusable Surgical Instruments 'Orthopaedic Instruments'	Class Ir & Im
Reusable Surgical Instruments 'General Surgery Instruments'	Class Ir & Im
For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements. For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	