

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

Device(s)	Risk Classification
Sharp Instruments, Reusable	Class Ir
Orthopaedic and Traumatological Surgery Instruments, Reusable	Class Ir
Orthopaedic and Traumatological Surgery Instruments, Reusable	Class Im, Class Ir
Surgical Screwdrivers, Reusable	Class Ir
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.	