

Device Schedule: Article 22.3 Systems and Procedure Pack

Device(s)	Highest Risk Classification within the System or Procedure Pack
Medicated Securement procedure packs	Class III
Medicated surgical drape procedure packs	Class III
Non-medicated Securement device procedure packs	Class IIa
Non-medicated Surgical drape procedure packs	Class Is
For Systems and Procedure Packs under Article 22.3, the Notified Body conformity assessment is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.	