

Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12 Administer and/or remove a medicinal substance	Intended purpose
Volumetric Infusion Pumps	Volumetric Infusion Pumps intended for use by medical staff for the purpose of controlling infusion rate and volume.
Infusion Instruments – Software Accessories	Software application intended to transfer data sets to, and infusion data from, compatible BD infusion products via a network connection.
Class IIb	Intended purpose
Infusion Instruments – Hardware Accessories	Accessories intended to be used within the hospital environment to provide mounting, power, and communication support to the compatible BD infusion pumps, including the transmission of infusion data.

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

Device(s)	Risk Classification
Sterile Single-use Infusion Kits	Class IIa
Sterile Single-use Infusion Syringes	Class IIa
Sterile Adapters and Connectors	Class IIa
Sterile Extension Sets	Class IIa
Sterile Stopcocks	Class IIa
Sterile Systems for Reconstitution and Administration of Pharmaceuticals	Class IIa
Sterile Adapters and Connectors	Class Is
Sterile Single-use Infusion Kits	
Sterile Systems for Reconstitution and Administration of Pharmaceuticals	
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	