

## Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Hollow Fiber Hemodialyzer Synthetic membrane UHF < 18 ml/h/mmHg	Hollow Fiber Hemodialyzers are used for adult patients with acute or chronic renal failure. It is intended to be used for hemodialysis treatment
Hollow Fiber Hemodialyzer Synthetic membrane UHF = 18 - 35 ml/h/mmHg	Hollow Fiber Hemodialyzers are used for adult patients with acute or chronic renal failure. It is intended to be used for hemodialysis treatment
Hollow Fiber Hemodialyzer Synthetic membrane UHF > 35 ml/h/mmHg	Hollow Fiber Hemodialyzers are used for adult patients with acute or chronic renal failure. It is intended to be used for hemodialysis treatment and Hemodiafiltration treatment.
Hollow Fiber Hemofilter Synthetic membrane UHF < 18 ml/h/mmHg	Hollow Fiber Hemofilter are used for pediatric and adult patients with renal failure. It is intended to be used for CRRT treatment.
Hollow Fiber Hemofilter Synthetic membrane UHF = 18 - 35 ml/h/mmHg	Hollow Fiber Hemofilter are used for pediatric and adult patients with renal failure. It is intended to be used for CRRT treatment.
Hollow Fiber Hemofilter Synthetic membrane UHF > 35 ml/h/mmHg	Hollow Fiber Hemofilter are used for pediatric and adult patients with renal failure. It is intended to be used for CRRT treatment.
Dialysis Concentrate, Basic Solutions, Powder Sodium Bicarbonate Container (Cartridge and Bag)	Bicarbonate cartridges/bags are intended to be used during hemodialysis treatments for Bicarbonate-based hemodialysis solutions. It must always be used together with a acid concentrate.
Dialysis Cleaning Cartridge	Disinfection and decalcification of the fluid path of the hemodialysis machine.

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

<b>Device(s)</b>	<b>Risk Classification</b>
Arterial and Venous Bloodlines	Class IIa
Infusion Set	Class IIa
Bacterial and Endotoxin Retention filter and set	Class IIa
Arterial Venous Dialysis Fistula Needle	Class IIa