

Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
3M™ Tegaderm™ Antimicrobial Dressing (containing chlorhexidine gluconate)	See MDR 725198
Tegaderm CHG Dressing Family	See MDR 725050
Ioban™ 2 Antimicrobial Incise Drape	See MDR 725053
Class IIb	Intended purpose
Instruments for function exploration and therapeutic interventions	Indicated for hypothermic patients or normothermic patients for whom induced hypothermia or localized temperature therapy is clinically indicated and can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. Devices can be used with adult and pediatric patients. Intended to prevent and treat hypothermia and can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. Devices can be used with adult and pediatric patients.
Electrosurgical dual patient pads (neutral electrodes), single use	Electrosurgical Patient Plates provide a safe return path for electrosurgical current during surgical application using electrosurgery.

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

Device(s)	Risk Classification
Devices for sterilization with Ethylene Oxide	Class IIa
Disinfectants, Antiseptics, sterilizing agents and detergents for medical devices-Other	Class IIa