

Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
Sidus Stem-Free Shoulder	See MDR 752593
CLS® Spotorno® Hip Stem	See MDR 753811
Alloclassic® Hip Stems	See MDR 753802
Innex® Knee System	See MDR 753809
Ceramic Femoral Heads	See MDR 753899
Avenir® Müller Cemented Hip Stem	See MDR 753813
CoCr femoral heads	See MDR 753875
Allofit Alloclassic Shell	See MDR 753888
BioloX Delta Taper Liner	See MDR 753944
Polyethylene Revision Liners	See MDR 753898
Alpha Inserts	See MDR 753907
Original M.E. Müller Low Profile Cup	See MDR 754006
Avenir Müller Uncemented Hip Stems	See MDR 753925
Wagner Cone Prosthesis® Hip Stem and Wagner SL Revision® Hip Stem	See MDR 753903
Burch-Schneider Reinforcement Cage	See MDR 753941
Original M.E. Müller Roof Reinforcement Ring	
Zimmer Reinforcement Ring with Hook	
Zimmer Reinforcement Ring with Hook and Cranial Flange	
Hip Unipolar and Modular Bipolar Heads	See MDR 754011
Protasul S-30 Heads	See MDR 753929
MS30 Stems & Centralizers	See MDR 753910
Original M.E. Müller Straight Stem	See MDR 753909
Fitmore Hip Stems	See MDR 753940

Class IIb, Implantable, Well-established technologies	Intended purpose
Bone Fixation Nails	Intended for temporary internal fixation and stabilization of fractures or osteotomies
Osteosynthesis screw-plate system	Treatment of fractures and osteotomies
Hip prosthesis - Accessories	Hip arthroplasty
Bone Fixation Wires	Temporary fixation of bone fractures, skeletal traction as anchorage, and bone reconstruction.

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

Device(s)	Risk Classification
Reusable surgical instruments 'Orthopaedic instruments'	Class Ir
Custom made 'Hip prosthesis'	Custom-made Class III implantable
Custom made 'Knee prosthesis'	Custom-made Class III implantable
Custom made 'Shoulder prosthesis'	Custom-made Class III implantable
Custom made 'Wrist prosthesis'	Custom-made Class III implantable
Custom made 'Elbow prosthesis'	Custom-made Class III implantable
Sterile surgical instruments 'Orthopaedic instruments'	Class Is
Surgical instruments with measuring function 'Orthopaedic instruments'	Class Im
Orthopaedic Instrumentation, Sterile and Non-sterile	Class IIa
Orthopaedic device trials	Class IIa
Sterile, reusable surgical instruments 'Orthopaedic instruments'	Class Is, Class Ir

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to 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.