

FDA REGISTRATION NUMBER: **3006946276**

LAST VALIDATED: November 07, 2024

STATUS: **Valid**

VALID 2025 U.S. FDA Medical Device Establishment Registration

MEDISTRI SA

ESTABLISHMENT INFORMATION

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LISTINGS ON FILE WITH FDA

Device Name	Product Code	Status	Last Validated
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Drug-Eluting Peripheral Transluminal Angioplasty Catheter	ONU	Valid	November 06, 2024
Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal/Polymer	HSX	Valid	November 06, 2024
Catheter, Continuous Flush	KRA	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Staple, Fixation, Bone	JDR	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Prosthesis, Hip, Semi-Constrained, Uncemented, Metal / Polymer, Non-Porous, Calcium Phosphate	MEH	Valid	November 06, 2024
Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented	LZO	Valid	November 06, 2024
Screw, Fixation, Bone	HWC	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Suture, Absorbable, Synthetic, Polyglycolic Acid	GAM	Valid	November 06, 2024

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Device Name	Product Code	Status	Last Validated
Screw, Fixation, Bone	HWC	Valid	November 06, 2024
Pin, Fixation, Smooth	HTY	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Screw, Fixation, Bone	HWC	Valid	November 06, 2024
Instrument, Vitreous Aspiration And Cutting, Ac-Powered	HQE	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer /Metal/Polymer	JWH	Valid	November 06, 2024
Prosthesis, Knee, Patello/Femoral, Semi-Constrained, Cemented, Metal/Polymer	KRR	Valid	November 06, 2024
Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented	LPH	Valid	November 06, 2024
Suture, Nonabsorbable, Synthetic, Polyethylene	GAT	Valid	November 06, 2024
Wire, Guide, Catheter	DQX	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Catheter, Peripheral, Atherectomy	MCW	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Guide, Surgical, Instrument	FZX	Valid	November 06, 2024
Prosthesis, Hip, Semi-Constrained, Uncemented, Metal / Polymer, Non-Porous, Calcium Phosphate	MEH	Valid	November 06, 2024
Instrument, Surgical, Orthopedic, Ac-Powered Motor And Accessory/Attachment	HWE	Valid	November 06, 2024
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer /Metal/Polymer	JWH	Valid	November 06, 2024
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Device Name	Product Code	Status	Last Validated
Cannula, Ophthalmic	HMX	Valid	06, 2024
Screw, Fixation, Bone	HWC	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Staple, Fixation, Bone	JDR	Valid	November 06, 2024
Screw, Fixation, Bone	HWC	Valid	November 06, 2024
Staple, Fixation, Bone	JDR	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer	KRO	Valid	November 06, 2024
Lens, Guide, Intraocular	KYB	Valid	November 06, 2024
Folders And Injectors, Intraocular Lens (Iol)	MSS	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Staple, Fixation, Bone	JDR	Valid	November 06, 2024
Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented	LZO	Valid	November 06, 2024
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer /Metal/Polymer	JWH	Valid	November 06, 2024
Suture, Nonabsorbable, Synthetic, Polyethylene	GAT	Valid	November 06, 2024
Suture, Nonabsorbable, Synthetic, Polyethylene	GAT	Valid	November 06, 2024
Catheter, Peripheral, Atherectomy	MCW	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer /Metal/Polymer	JWH	Valid	November 06, 2024
Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal/Polymer	HSX	Valid	November 06, 2024

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Device Name	Product Code	Status	Last Validated
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented	LPH	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Arthroscope	HRX	Valid	November 06, 2024
Screw, Fixation, Bone	HWC	Valid	November 06, 2024
Screw, Fixation, Bone	HWC	Valid	November 06, 2024
Suture, Surgical, Absorbable, Polydioxanone	NEW	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Screw, Fixation, Bone	HWC	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Staple, Fixation, Bone	JDR	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Folders And Injectors, Intraocular Lens (Iol)	MSS	Valid	November 06, 2024
Folders And Injectors, Intraocular Lens (Iol)	MSS	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer /Metal/Polymer	JWH	Valid	November 06, 2024
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer /Metal/Polymer	JWH	Valid	November 06, 2024
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Device Name	Product Code	Status	Last Validated
Pin, Fixation, Smooth	HTY	Valid	06, 2024
Intraocular Lens	HQL	Valid	November 06, 2024
Ophthalmic Femtosecond Laser	OOE	Valid	November 06, 2024
Stent, Superficial Femoral Artery	NIP	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Washer, Bolt Nut	HTN	Valid	November 06, 2024
Dressing, Wound, Drug	FRO	Valid	November 06, 2024
Catheters, Transluminal Coronary Angioplasty, Percutaneous	LOX	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Prosthesis, Hip, Cement Restrictor	JDK	Valid	November 06, 2024
Orthopedic Stereotaxic Instrument	OLO	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Drug-Coated Peripheral Transluminal Angioplasty Catheter	PRC	Valid	November 06, 2024
Staple, Fixation, Bone	JDR	Valid	November 06, 2024
Screw, Fixation, Bone	HWC	Valid	November 06, 2024
Staple, Fixation, Bone	JDR	Valid	November 06, 2024
Reamer	HTO	Valid	November 06, 2024
Folders And Injectors, Intraocular Lens (Iol)	MSS	Valid	November 06, 2024
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer /Metal/Polymer	JWH	Valid	November 06, 2024
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer /Metal/Polymer	JWH	Valid	November 06, 2024
Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented	KWY	Valid	November 06, 2024

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Device Name	Product Code	Status	Last Validated
Prosthesis, Hip, Semi-Constrained, Uncemented, Metal / Polymer, Non-Porous, Calcium Phosphate	MEH	Valid	November 06, 2024
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer /Metal/Polymer	JWH	Valid	November 06, 2024
Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented	LZO	Valid	November 06, 2024
Pin, Fixation, Smooth	HTY	Valid	November 06, 2024
Staple, Fixation, Bone	JDR	Valid	November 06, 2024
Screw, Fixation, Bone	HWC	Valid	November 06, 2024
Pin, Fixation, Smooth	HTY	Valid	November 06, 2024
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer /Metal/Polymer	JWH	Valid	November 06, 2024
Folders And Injectors, Intraocular Lens (Iol)	MSS	Valid	November 06, 2024
Screw, Fixation, Bone	HWC	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer	KRO	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Suture, Nonabsorbable, Synthetic, Polyethylene	GAT	Valid	November 06, 2024
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Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	06, 2024
Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal/Polymer	HSX	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Suture, Surgical, Absorbable, Polydioxanone	NEW	Valid	November 06, 2024
Suture, Nonabsorbable, Synthetic, Polyethylene	GAT	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Peripheral Mechanical Thrombectomy With Aspiration	QEW	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Orthopedic Stereotaxic Instrument	OLO	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented	LPH	Valid	November 06, 2024
Shoulder Prosthesis, Reverse Configuration	PHX	Valid	November 06, 2024
Screw, Fixation, Bone	HWC	Valid	November 06, 2024
Suture, Surgical, Absorbable, Polydioxanone	NEW	Valid	November 06, 2024
Orthopedic Manual Surgical Instrument	LXH	Valid	November 06, 2024
Prosthesis, Hip, Semi-Constrained, Uncemented, Metal / Polymer, Non-Porous, Calcium Phosphate	MEH	Valid	November 06, 2024
Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented	LZO	Valid	November 06, 2024
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer /Metal/Polymer	JWH	Valid	November 06, 2024
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer /Metal/Polymer	JWH	Valid	November 06, 2024
Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented	LPH	Valid	November 06, 2024

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Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Folders And Injectors, Intraocular Lens (Iol)	MSS	Valid	November 06, 2024
Pin, Fixation, Smooth	HTY	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented	KWS	Valid	November 06, 2024
Fastener, Fixation, Biodegradable, Soft Tissue	MAI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Suture, Surgical, Absorbable, Polydioxanone	NEW	Valid	November 06, 2024
Folders And Injectors, Intraocular Lens (Iol)	MSS	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Screw, Fixation, Bone	HWC	Valid	November 06, 2024
Suture, Nonabsorbable, Synthetic, Polyethylene	GAT	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer /Metal/Polymer	JWH	Valid	November 06, 2024
Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer	KRO	Valid	November 06, 2024
Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal/Polymer	HSX	Valid	November 06, 2024
Fastener, Fixation, Nondegradable, Soft Tissue	MBI	Valid	November 06, 2024
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Orthopedic Stereotaxic Instrument	OLO	Valid	06, 2024
Folders And Injectors, Intraocular Lens (Iol)	MSS	Valid	November 06, 2024