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Zepf Medical Instruments GmbH
Gunningerstrasse 21
78606 Seitingen-Oberflacht
Germany

October 30th, 2018

Confirmation of completed 2019 Annual Registration with FDA

To Whom It May Concern:

This letter is to confirm that Zepf Medical Instruments GmbH is registered with the US Food and Drug Administration. The current registration of Zepf Medical Instruments GmbH is valid through December 31st, 2019. Please feel free to contact me with any questions.

Sincerely,


Beate Weiss-Krull, Esq.

✓ Facility

✓ Products Listing

Annual Registration Successful

Facility: ZEPF MEDICAL INSTRUMENTS GMBH, SEITINGEN-OBERFLACHT, Baden-Wurttemberg, GERMANY

You have successfully updated your registration and listing information for 2019.

Your registration will be valid through Dec 31, 2019.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2019.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 9045716.

Facility Information

Registration Number:	3003244954
Initial Importer:	N
Facility Name:	ZEPF MEDICAL INSTRUMENTS GMBH
Address:	21 GUNNINGER ST., SEITINGEN-OBERFLACHT, Baden-Wurttemberg, D-78606, GERMANY
DUNS Number:	
Foreign Trade Zone:	N
Facility URL:	
Other Business Trade Name(s):	

Owner/Operator Information

Owner/Operator Number:	9045716
Contact Name:	Jochen - ZEPF
Company:	ZEPF MEDICAL INSTRUM
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Official Correspondent Information

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United States Agent Information

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Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers
B093537	Exempt	HXY	BRACE, DRILL	Manufacturer	DE SOUTTER MEDICAL USA, Inc
B093539	Exempt	FTY	TAPE, MEASURING, RULERS AND CALIPERS	Manufacturer	DE SOUTTER MEDICAL USA, Inc MED SAVER, INC.
B093542	Exempt	HMX	Cannula, ophthalmic	Manufacturer	
B093544	Exempt	LGG	INSTRUMENT, CAST APPLICATION/REMOVAL, MANUAL	Manufacturer	
B093545	Exempt	HXN	APPLIER, CERCLAGE	Manufacturer	
B093546	Exempt	KDG	CHISEL (OSTEOTOME)	Manufacturer	
B093547	Exempt	JYF	CLAMP, OSSICLE HOLDING	Manufacturer	DE SOUTTER MEDICAL USA, Inc

					MED SAVER, INC. MAGNUM MEDICAL, INC. Surgical & Medical Specialties
B093528	Exempt	GFA	BLADE, SAW, GENERAL & PLASTIC SURGERY, SURGICAL	Manufacturer	
B093529	Exempt	GES	BLADE, SCALPEL	Manufacturer	
B093530	Exempt	EMI	FILE, BONE, SURGICAL	Manufacturer	DE SOUTTER MEDICAL USA, Inc MED SAVER, INC.
B093535	Exempt	HWX	TAP, BONE	Manufacturer	Surgical Instrument Distributing - DGI Instruments
B093536	Exempt	FAX	BOUGIE, UROLOGICAL	Manufacturer	MED SAVER, INC.
B093559	Exempt	KBL	DEPRESSOR, METAL TONGUE, SURGICAL	Manufacturer	
B093560	Exempt	GFD	DERMATOME	Manufacturer	
B093561	Exempt	HNW	Dilator, lachrymal	Manufacturer	
B093563	Exempt	GDI	DISSECTOR, SURGICAL, GENERAL & PLASTIC SURGERY	Manufacturer	MED SAVER, INC. DE SOUTTER MEDICAL USA, Inc
B093564	Exempt	KBM	DISSECTOR, TONSIL	Manufacturer	
B093565	Exempt	GFC	DRIVER, SURGICAL, PIN	Manufacturer	
B093566	Exempt	JYD	CHISEL, MASTOID	Manufacturer	RMedical Inc.
B093567	Exempt	JYT	PICK, MICROSURGICAL EAR	Manufacturer	

B093568	Exempt	JZB	SCISSORS, EAR	Manufacturer	DE SOUTTER MEDICAL USA, Inc
B093569	Exempt	JZD	SNARE, EAR	Manufacturer	
B093548	Exempt	FHA	CLAMP, PENILE	Manufacturer	
B093550	Exempt	HGC	CLAMP, UTERINE	Manufacturer	
B093552	Exempt	HNJ	Punch, corneo-scleral	Manufacturer	
B093554	Exempt	HTF	CURETTE	Manufacturer	MAGNUM MEDICAL, INC. MED SAVER, INC. DE SOUTTER MEDICAL USA, Inc Surgical & Medical Specialties
B093555	Exempt	KBJ	CURETTE, ADENOID	Manufacturer	
B093556	Exempt	JYG	CURETTE, EAR	Manufacturer	
B093557	Exempt	KAP	CURETTE, NASAL	Manufacturer	
B093558	Exempt	HCY	CURETTE, UTERINE	Manufacturer	MED SAVER, INC. Surgical & Medical Specialties
B093502	Exempt	HRH	Trephine, manual, ophthalmic	Manufacturer	
B093503	Exempt	EML	CHISEL, BONE, SURGICAL	Manufacturer	DE SOUTTER MEDICAL USA, Inc MAGNUM MEDICAL, INC. Surgical Instrument Distributing - DGI Instruments RMedical Inc.

B093515	Exempt	GDN	KNIFE, AMPUTATION	Manufacturer	MED SAVER, INC.
B093518	Exempt	HBT	APPLIER, HEMOSTATIC CLIP	Manufacturer	DE SOUTTER MEDICAL USA, Inc
B093519	Exempt	GDO	Applier, surgical, clip	Manufacturer	
B093520	Exempt	EFK	FORCEPS, ARTICULATION PAPER	Manufacturer	
B093521	Exempt	GDM	NEEDLE, ASPIRATION AND INJECTION, REUSABLE	Manufacturer	
B093522	Exempt	HWJ	AWL	Manufacturer	SUrgical Instrument Distributing - DGI Instruments
B093523	Exempt	ECS	PUSHER, BAND, ORTHODONTIC	Manufacturer	
B093524	Exempt	FNY	BASIN, EMESIS	Manufacturer	MED SAVER, INC.
B093525	Exempt	HFB	FORCEPS, BIOPSY, GYNECOLOGICAL	Manufacturer	MED SAVER, INC.
B093504	Exempt	HOE	Caliper, ophthalmic	Manufacturer	Surgical Instrument Distributing - DGI Instruments
B093505	Exempt	JYC	CANNULA, EAR	Manufacturer	
B093507	Exempt	KCG	DILATOR, TRACHEAL	Manufacturer	
B093509	Exempt	DWS	INSTRUMENTS, SURGICAL, CARDIOVASCULAR	Manufacturer	DE SOUTTER MEDICAL USA, Inc MED SAVER, INC. MAGNUM MEDICAL, INC. Cunningham Woodland

					Inc. Surgical Instrument Distributing - DGI Instruments MSI Precision Spezialty Instrument RMedical Inc.
B093510	Exempt	HDF	SPECULUM, VAGINAL, METAL	Manufacturer	MED SAVER, INC. MAGNUM MEDICAL, INC. Surgical & Medical Specialties RMedical Inc.
B093511	Exempt	MDM	INSTRUMENT, MANUAL, SURGICAL, GENERAL USE	Manufacturer	DE SOUTTER MEDICAL USA, Inc MAGNUM MEDICAL, INC. MSI Precision Spezialty Instrument HMC Surgical RMedical Inc. Cunningham Woodland Inc. Surgical & Medical Specialties
B093512	Exempt	KBH	ADENOTOME	Manufacturer	
B093513	Exempt	EKI	CARRIER, AMALGAM, OPERATIVE	Manufacturer	
B093514	Exempt	EKG	CONDENSER, AMALGAM AND FOIL, OPERATIVE	Manufacturer	
B093933	Exempt	HDJ	SCISSORS, UMBILICAL	Manufacturer	

B093934	Exempt	HXX	SCREWDRIVER	Manufacturer	DE SOUTTER MEDICAL USA, Inc
B093935	Exempt	KGB	MASK, OXYGEN, NON-REBREATHING	Manufacturer	
B093936	Exempt	GXJ	PUNCH, SKULL	Manufacturer	
B093937	Exempt	GAE	SNARE, SURGICAL	Manufacturer	
B093938	Exempt	KBZ	SNARE, TONSIL	Manufacturer	
B093939	Exempt	GAI	STRIPPER, VEIN, REUSABLE	Manufacturer	Surgical & Medical Specialties
B093940	Exempt	FSM	TRAY, SURGICAL, INSTRUMENT	Manufacturer	Surgical & Medical Specialties
B093941	Exempt	KCP	SYRINGE, ENT	Manufacturer	
B093942	Exempt	KYZ	SYRINGE, IRRIGATING (NON DENTAL)	Manufacturer	
B093923	Exempt	FFQ	SPECULUM, RECTAL	Manufacturer	DE SOUTTER MEDICAL USA, Inc
B093924	Exempt	EIS	REMOVER, CROWN	Manufacturer	
B093925	Exempt	EIG	RETRACTOR, ALL TYPES	Manufacturer	
B093926	Exempt	FFO	RETRACTOR, SELF-RETAINING	Manufacturer	MAGNUM MEDICAL, INC. MED SAVER, INC. DE SOUTTER MEDICAL USA, Inc Surgical & Medical Specialties Surgical Instrument Distributing - DGI Instruments
B093927	Exempt	FNS	RING CUTTER	Manufacturer	MAGNUM

					MEDICAL, INC.
B093928	Exempt	HNH	RING, OPHTHALMIC (FLIERINGA)	Manufacturer	
B093930	Exempt	HRR	SCISSORS, ORTHOPEDIC, SURGICAL	Manufacturer	MED SAVER, INC. DE SOUTTER MEDICAL USA, Inc MAGNUM MEDICAL, INC. Surgical & Medical Specialties RMedical Inc.
B093931	Exempt	LRW	SCISSORS, GENERAL, SURGICAL	Manufacturer	MED SAVER, INC. DE SOUTTER MEDICAL USA, Inc MAGNUM MEDICAL, INC. Surgical Instrument Distributing - DGI Instruments RMedical Inc. HMC Surgical Cunningham Woodland Inc.
B093932	Exempt	EGN	SCISSORS, SURGICAL TISSUE, DENTAL	Manufacturer	
B127690	Exempt	EFL	FORCEPS, DRESSING, DENTAL	Manufacturer	
B127691	Exempt	HNF	SCISSORS, OPHTHALMIC	Manufacturer	MED SAVER, INC.
B127692	Exempt	KBG	TROCAR, SINUS	Manufacturer	
B127693	Exempt	LGH	INSTRUMENT, CAST	Manufacturer	

			REMOVAL, AC-POWERED		
B093946	Exempt	KCB	TUBE, TONSIL SUCTION	Manufacturer	
B093947	Exempt	KCY	TOURNIQUET, PNEUMATIC	Manufacturer	
B093948	Exempt	EPE	BRUSH, CLEANING, TRACHEAL TUBE	Manufacturer	
B127687	Exempt	GEN	FORCEPS, GENERAL & PLASTIC SURGERY	Manufacturer	DE SOUTTER MEDICAL USA, Inc MED SAVER, INC. MAGNUM MEDICAL, INC. RMedical Inc. Surgical Instrument Distributing - DGI Instruments HMC Surgical Cunningham Woodland Inc. Surgical Instrument Distributing - DGI Instruments
B093949	Exempt	KCI	TROCAR, TRACHEAL	Manufacturer	
B127684	Exempt	HTD	FORCEPS	Manufacturer	DE SOUTTER MEDICAL USA, Inc Cunningham Woodland Inc. Surgical & Medical Specialties HMC Surgical
B127685	Exempt	JXX	FORCEPS, WIRE CLOSURE, ENT, STERILE	Manufacturer	

B127680	Exempt	HNR	Forceps, ophthalmic	Manufacturer	MAGNUM MEDICAL, INC.
B127681	Exempt	EJG	FORCEPS, RUBBER DAM CLAMP	Manufacturer	
B127676	Exempt	HXC	WRENCH	Manufacturer	
B127677	Exempt	HXZ	CUTTER, WIRE	Manufacturer	DE SOUTTER MEDICAL USA, Inc MED SAVER, INC. Surgical & Medical Specialties Surgical Instrument Distributing - DGI Instruments
B127678	Exempt	KAE	FORCEPS, ENT	Manufacturer	DE SOUTTER MEDICAL USA, Inc MAGNUM MEDICAL, INC. MED SAVER, INC. RMedical Inc.
B093580	Exempt	EMH	FORCEPS, RONGEUR, SURGICAL	Manufacturer	DE SOUTTER MEDICAL USA, Inc MAGNUM MEDICAL, INC. Surgical & Medical Specialties Surgical Instrument Distributing - DGI Instruments RMedical Inc.
B093581	Exempt	KBN	GAG, MOUTH	Manufacturer	

B093582	Exempt	HTJ	GAUGE, DEPTH	Manufacturer	Surgical Instrument Distributing - DGI Instruments
B093583	Exempt	KAQ	GOUGE, NASAL, ENT	Manufacturer	
B093584	Exempt	KBO	GUILLOTINE, TONSIL	Manufacturer	
B127672	Exempt	HXS	TWISTER, WIRE	Manufacturer	
B127673	Exempt	HDM	PACKER, UTERINE	Manufacturer	
B093585	Exempt	HSS	HALTER, HEAD, TRACTION	Manufacturer	
B127674	Exempt	HHM	SOUND, UTERINE	Manufacturer	MED SAVER, INC. MAGNUM MEDICAL, INC. Surgical & Medical Specialties
B093586	Exempt	FZY	HAMMER, SURGICAL	Manufacturer	MAGNUM MEDICAL, INC. MED SAVER, INC. DE SOUTTER MEDICAL USA, Inc Surgical & Medical Specialties
B093587	Exempt	GDZ	HANDLE, SCALPEL	Manufacturer	DE SOUTTER MEDICAL USA, Inc
B093588	Exempt	HPP	Headlamp, operating, battery-operated	Manufacturer	
B093589	Exempt	HRQ	HEMOSTAT	Manufacturer	
B093570	Exempt	EPY	SPECULUM, ENT	Manufacturer	MED SAVER, INC.
B093571	Exempt	JZE	SPOON, EAR	Manufacturer	

B093573	Exempt	KAD	ELEVATOR, ENT	Manufacturer	
B093574	Exempt	EMJ	ELEVATOR, SURGICAL, DENTAL	Manufacturer	Cunningham Woodland Inc.
B093576	Exempt	HNT	Erisophake	Manufacturer	
B093577	Exempt	EMG	FORCEPS, TOOTH EXTRACTOR, SURGICAL	Manufacturer	
B093578	Exempt	EMR	FILE, PERIODONTIC	Manufacturer	
B093579	Exempt	GEO	FILE, SURGICAL, GENERAL & PLASTIC SURGERY	Manufacturer	MED SAVER, INC. Surgical & Medical Specialties RMedical Inc.
B093911	Exempt	KBR	NEEDLE, TONSIL SUTURING	Manufacturer	
B093913	Exempt	JYR	NIPPER, MALLEUS	Manufacturer	
B093917	Exempt	ERA	OTOSCOPE	Manufacturer	
B093918	Exempt	HXI	PASSER, WIRE, ORTHOPEDIC	Manufacturer	
B093919	Exempt	GWY	PINWHEEL	Manufacturer	
B093920	Exempt	HXB	PROBE	Manufacturer	DE SOUTTER MEDICAL USA, Inc RMedical Inc. Surgical & Medical Specialties
B093921	Exempt	LWK	RAZOR, SURGICAL	Manufacturer	
B093902	Exempt	CCQ	NEBULIZER, MEDICINAL, NON-VENTILATORY (ATOMIZER)	Manufacturer	
B093903	Exempt	HPN	Magnet, permanent	Manufacturer	
B093904	Exempt	GEY	MOTOR, SURGICAL INSTRUMENT, AC-POWERED	Manufacturer	
B093905	Exempt	EAX	MIRROR, MOUTH	Manufacturer	

B093906	Exempt	KAY	PUNCH, NASAL	Manufacturer	RMedical Inc.
B093907	Exempt	KBC	SAW, NASAL	Manufacturer	
B093908	Exempt	KBE	SNARE, NASAL	Manufacturer	
B093590	Exempt	HNQ	Hook, ophthalmic	Manufacturer	Surgical & Medical Specialties Surgical Instrument Distributing - DGI Instruments
B093591	Exempt	GDG	HOOK, SURGICAL, GENERAL & PLASTIC SURGERY	Manufacturer	MAGNUM MEDICAL, INC. DE SOUTTER MEDICAL USA, Inc MED SAVER, INC. Surgical & Medical Specialties Cunningham Woodland Inc.
B093592	Exempt	EIY	INSTRUMENT, FILLING, PLASTIC, DENTAL	Manufacturer	
B093593	Exempt	KDC	INSTRUMENT, SURGICAL, DISPOSABLE	Manufacturer	
B093594	Exempt	JYP	KNIFE, MYRINGOTOMY	Manufacturer	
B093595	Exempt	KAS	KNIFE, NASAL	Manufacturer	
B093596	Exempt	HNN	Knife, ophthalmic	Manufacturer	
B093597	Exempt	EMF	KNIFE, SURGICAL	Manufacturer	
B093598	Exempt	JBS	TIMER, GENERAL LABORATORY	Manufacturer	
B093599	Exempt	HNL	Probe, lachrymal	Manufacturer	MED SAVER, INC.
B093910	Exempt	GDL	NEEDLE, SUTURING, REUSABLE	Manufacturer	

Date of Initial Registration: 2001-04-23 11:33:11.0
