

# CE-Certificate

## Full quality assurance system

The conformity assessment body for medical devices of Swiss TS  
Technical Services AG hereby certifies that:

**AUSTOS MEDICAL**  
17175 Von Karman Ave  
Suite 101 Irvine, California 92614  
United States

has introduced and applies a full quality assurance system  
according to annex II.3 of directive 93/42 EEC, including  
the directive 2007/47/EC

for the products

### according to annex

The full quality assurance system covers design, manufacturing and final inspection of the products according to the requirements of annex II.3 of the directive 93/42 EEC. The quality assurance system is regularly controlled by Swiss TS Technical Services AG according to annex II.5.

**Registration number:** 05-314-224  
**First certification:** 06.07.2011  
**Valid until:** 05.07.2020

**CE marking of conformity:**

**CE1253**



Heinrich A. Bieler  
Head of the certification body

Wallisellen, 22.06.2017

Notified Body 1253  
Swiss TS Technical Services AG  
Richtstrasse 15  
CH-8304 Wallisellen  
Swiss TS, a company of SVTI and TUV SUD



SCESm013

# Product list

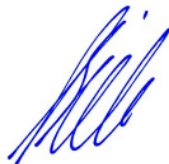
## To CE-Certificate – Full quality assurance system

Term	UMDNS	Class
Plates, Bone	13-050	Ib
Fixation Device, Internal, Nails	16-078	Ib
Screws, Bone	16-101	Ib
Fixation Device, Internal, Stables	16-103	Ib
Wires, Bone	16-104	Ib
Fixation Device, Internal, Pin	16-085	Ib
Fracture Fixation System, external	15-767	Ib
Orthopaedic burs	17-995	Ia
Saw Blades	13-449	Ia
Handpiece, surgical	17-949	Ia
Shaver System, Arthroscopy	17-918	Ia
Shaver Blades	17-117	Ia
Pump System, Arthroscopy	17-223	Ia
Arthroscopes, rigid	10-198	Ia

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Term	UMDNS	Class
HF-Instruments	11-500	Ib
Diamond Rotary Instruments	11-237	Ila
Instruments for suction and irrigation	16-883	Ila
Abdominal retractors, retractors	15-242	Ila
Trocar	15-260	Ila
Micromotor-Drivers	16-868	Ila
Rib Spreaders	13-709	Ila
Orthopaedic drills	11-331	Ila
Lasers surgical and accessories	16-943	Ila
Orthopaedic reamers	13-297	Ila
HF-Generators	11-490	Ila
Suction and Irrigation Pumps with accessoires	13-845	Ila
Insufflatores with accessoires	16-849	Ila
Microsurgical Instruments	15-621	Ila
Endoscopes (Video)	17-663	Ila

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Term	UMDNS	Class
Sterile single use products	17-684	Ila
Surgical Instrument Container Systems	16-349	Ila
Forceps, Grasping, Flexible Endoscopic	15-628	Ilb
Cystoscopes, Flexible	17-144	Ila
Light Sources, Fiberoptic, Flexible Endoscopic	12-343	Ila
Cameras, Endoscopic	15-748	Ila
Knives, Plasma	15-796	Ilb
Sutures	16-584	III
Video Image Processors, Endoscopic	18-034	Ila
Endoscope/Camera Adapters	18-104	Ila
Laser Fiber Guides, Endoscopic	18-097	Ila
Clips, Vascular	10-174	III
Lithotripters, Ultrasonic	16-230	Ila
Ultrasonic Surgical Cutter/Coagulators	18-049	Ila
Electrocardiographs	11-407	Ilb

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