



'CE' CONFORMITY DECLARATION

Frame of the EC directive numbered 93/42/EEG;

Producer : **Sueda Danışmanlık ve Dış Tic. Ltd. Şti.**

Address : **Maslak Meydan Sokak Veko Giz Plaza No:3/43 Kat:13
Maslak / İstanbul**

Product Description : **Surgical Instruments, Sterilization Container Systems : Class 1 Product**

Directive

93/42 / EEG Medical Device Directive

Product Classification 93/42 EEG was carried out in accordance with Annex 7.

About medical products that do not in contact with tissue and body fluids number 1 regulation has been decided in accordance with Annex IX regulation. (Not fused)

This declaration DIN, EN, TS, ISO 9001: 2008, ISO 13485: 2003, 93/42 EEG certificated quality system has been arranged based.

Hereby Sueda Danışmanlık ve Dış Tic. Ltd. Şti. declares that all products which defined as class 1 of the European Directive and 'CE' marked are ensure compliance with European standards

This statement applies to all types of products listed below Class 1 surgical tools.

Product Types:

Model	Bottom Model Name
Spekulums	Ear-Nose-Eyes-vaginal and rectal speculum, mouth openers
Needle Holders	Standard, Micro and Wire needle holders, Suture instruments
Tweezers / Clamps / Forceps	Hemostatic-Artery-dissection-vein-Pad-tissue forceps, intestinal forceps, bone forceps, rongeur forceps, Alligator forceps, biopsy forceps, pulling tooth davy, Hysterectomy forceps, Sponge and clamps
Collets	Tissue-Dissection-Eyes-Micro-Suture-Bipolar and dentist forceps
Scissors	Surgery-Dissection-Vein and Micro scissors, thread and wire scissors, Plaster scissors, Bone cutter scissors
Curettes	Bone-uterine-ear-eye-nose and teeth Curettes
Bone Cutters / Drills	Osteotomes, Chisells, Gujs, Trepanns, Mills, Drills, Reamers, Buffers
General Orthopedic Surgical Instruments	Screwdrivers, Traction Tools and Tendons Removers, Wire Crimping Tools, Shook and Removers
Elevators	Bone - tooth elevators
Retractors	Skin-Chest retractors, Automatic retractors, Hukes, Piks

Dilators	Probes, Urethral-Uterine-Bile Duct and Vessel Dilator, Trocars, Suction Tips, Biopsy Needles, Props
Hammers	Metal and Synthetic Hammers
Knives	Grips Scalpel, Scalpels, Surgical Blades, Dermatomes
Rongeurs / Punches	Kerrison Punches, Disc Punches, Bone Punches, Bone Rongeurs
Cardiovascular Surgical Instruments	Atromatik Clamps (vein clamp), Approximates their (vein holder)
Electro Surgical Instruments	Cold Light Source
Head Traction Instruments	Studded Head
Surgery motor hand apparatuses and headings	Surgery motor apparatuses and headings
Anatomy, Amputation and Autopsy Tools	Scissors, Clamps, Knives, Elevators, Osteotoms
Urology Instruments	Urology Scissors and Scoops, Urology Forceps, Clamps and Hooks, Bladder Instruments, Catheters and Catheter Introducing Instruments, Circumcision Instruments, Hilar Retractors, Prostatectomy Instruments, Urethrotome Instruments
Myoma Appliances	Knives, Reamers
Gynecology Instruments / Birth Tools	Curettes and Scoops, Forceps – Gynaecology, Instruments for Amnioscopy and for Micro Bloodletting, Myoma Screws and Knives, Uterine Probes and Sounds, Uterine Dilators, Vaginal Speculum and Retractors, Vulva, Urethral and Endocervical Spreaders
Dermatology Equipment	Dermatomes
Eye Surgery Instruments	Clamps, Forceps, Canulas, Scoops, Retractors, Punches, Knives, Scissors
Brain Surgery Instruments	Forceps and Spatulas, Aspirating and Irrigating Instruments, Hooks, Dissectors and Curettes , Retractors and Spreaders, Rongeurs, Neurosurgery Scissors, Skull Punches, Trephines and Wire Saws
ENT Surgical Instruments	Adenoid Curettes, Adenotomes, Mouth Gags, Retractors, Tonsil and Forceps and Punches, Tonsil Scissors, Tonsil Knives and Dissectors, Aspirating and Irrigating Instruments, Insufflators, Curettes, Levers, Probes and Hooks, Ear Scissors and Ear Snares, Raspatories and Elevators, Elevators and Raspatories, Punches and Rongeurs for Rhinoplasty, ENT Surgery Forceps, Suction Instruments, Saws
Sterilization Containers	Aluminum containers for sterilization
Wire Baskets	Washing tools and wires baskets for carrying of instrumnets
Indicator Tags	Container Labels with indicator
Security Seals	Container Security Seals
Silicon Mats	Silicon mats for container
Cups	Stainless Steel Cups
Tromels	Stainless Steel Sterilization Tromels
Storage Containers	Stainless Steel Storage Containers
Kidney Tubs	Stainless Steel Kidney Tubs
HOLDERS and Separators Accessories	Container apparatus holder and separator accessories
Sterilization Glands	Sterilization Glands

İstanbul 19.06.2015

**Quality Systems Manager
Mehmet Reşat ER**



**General Manager
Yakup DİKME**

**Sueda Danışmanlık
ve Dış Ticaret Ltd. Şti.**
Maslak Meydanı/SK. Yeke- Güz Plaza
No: 3/43-Kat: 4/5 Şişli-İSTANBUL
Tel:0212 705 36 16 Fax:0212 705 36 36
Maslak V.D. 782 062 5489

Thompson is registered trademark of Sueda Danışmanlık ve Dış Tic. Ltd. Şti.