



CE

## DECLARATION OF CONFORMITY

*Council Directive 93/42/ECC on Medical Devices;*

**Name of Producer :** Asel Tibbi Aletler Sanayi ve Ticaret Anonim Şirketi

**Address of Product Owner :** Köprübaşı Mah. Selanik Cad. No:255/1  
Tekkeköy / SAMSUN - TURKEY

**Product Description:** Sterilization Container Systems, Surgical Instruments (Class I)

**Brand :** ASELTECH

### Dirctive

*Council Directive 93/42/ECC on Medical Devices*

*Product classification is based on Annex VII of 93/42 ECC Directive*

*Medical devices which are not in contact directly with tissue and body fluids are decided according to Regulation I of Annex IX.*

*Standards: DIN, EN, TS, ISO 9001:2015, ISO 13485:2016*

*Herewith as "Asel Tibbi Aletler Sanayi ve ticaret Anonim Şirketi" declare that the products above mentioned are manufactured in accordance with the EC Medical Devices Directives 93/42 ECC.*

**Product Models:**

<i>Pattern</i>	<i>Sub Pattern Name</i>
Speculums and Mouth Gags	Ent- Eye-Vaginal-Rectal Speculums- Mouth Gags-Anuscopes-Sphincteroscopes-Proctoscope-
Needle and Wire Holders	Standard Needle Holder-Micro Needle Holder-Wire Holders
Forceps	Heamostatic-Artery-Dissection-Vessel-Sponge-Tissue Forceps, Intestinal Forceps, Bone Forceps, Rongeur Forceps, Ear Forceps, Biopsy Forceps, Hysterectomy Forceps, Towel Forceps Bronchus Forceps, Vascular Forceps, Grasping Forceps, Tendon Forceps, Dressing Forceps, Rectum Forceps, Haemorrhoidal Forceps, Gall Stone Forceps, Kidney Forceps, Uterine Forceps, Polypus and Ovum Forceps, Anastomosis Forceps
Forceps, Tissue Forceps	Tissue-Dissecting-Eye-Micro-Suture-Bipolar-Atraumatic Forceps
Scissors	Surgical-Dissecting-Vessel-Micro-Wire-Bandage-Bone-Tissue-Nasal-Ear-Gynaecology-Cartilage-Ligature-Tonsil-Rectal-Plate-

	Plaster-Eye-Rib-Vascular Scissors
Curettes	Bone-Uterine-Placenta-Ovum-Biopsy-Ent-Eye-Nasal-Gall Stone-Vacum Curettes
Bone Cutters	Osteotomes-Chisels-Gouges-Trepans
Perforators	Hand Drills and Twist Drills
General Orthopedical Surgical Inst.	Screw Drivers-Wire Traction Bows-Tendon Stripper-Wire Pliers
Elevators	Bone and Ent Elevators
Retractors	Skin-Abdominal-Thorax-Sternum-Atrium-Vein-Nerve-Vessel-Hooks-Dura-Wound-Trachea-Knee-Spatulas-Deep Surgery-Pelvis-Self Retaining-Laminectomy-Cervical-Lumbar-Micro-Bladder-Rectal-Root-Plaster Retractors
Dilators	Probes-Directors-Sond-Applicators-Uterine-Genito-Urinary-Vessel-Trocars-Biopsy Needles- Gall Duct-Tracheal Dilators
Mallets	All Surgical Mallets
Knives and Handles	Surgery Knives-Scalpel Handles-Brain Knives-Autopsy Knives-Fistula Knives-Cone Knives-Throat Knives-Cartilage Knives-Amputation and Resection Knives-Tonsil Knives-Trigeminal-Dura-Dermal Knives- Skin Grafting Knives-Dermatomes
Rongeurs / Punches	Kerrison Punches-Aorta Punches-Bone Punches-Ent Punches-Cervical Punches- Neurosurgical Punches-Disc Punches-Bone Rongeurs-Ent Rongeurs -Cervical Rongeurs - Neurosurgical Rongeurs -Disc Rongeurs
Electro Surgical Instruments	Cold Light Source, Bipolar Forceps
Raspatory	Rib-Bone-Anatomy-Autopsy-Ent- Orthopedic Rasps
Reamers and Tampers	Bone Reamers and Tampers
Bone Files	Bone Fand Ent Files
Osteotome / Chisels / Gouges	Bone Osteotom, Chisels and Gouges
Suction Cannula	Standard-Rectal-Ventriculopuncture Cannula-Coagulation-Irrigation-Nasal-Tonsil-Ear-Lateral Cannula and Suction Cannula
Wire saw and Wire Handle	Wire saw and Wire Handle
Clips / Clamps	Vessel Clips-Micro Clips-Approximators-Vascular Clips-Bulldog Clamps
Head Traction Instruments.	Skull Clamps
Surgical motors	Surgical motors
Anatomy, Amputation and Autopsy Instruments.	Scissors-Forceps-Kinives-Elevators-Osteotomes
Myoma Instruments.	Knives-Reamers
Dermatology Instruments.	Dermatomes- Dermal Knives- Skin Grafting Knives
Sterilization Containers	Stainless steel and aluminum model sterilization containers
Wire and Plate Baskets	Wire and plate baskets for washing and washing of instruments
Labels with Indicator	Sterilization Containers Labels with Indicator
Security Sears	Sterilization Containers Security Sears
Silicone Mats	Silicone Mats for Sterilization Containers
Stainless Steel Bowls and Trays	Stainless Steel Bowls- Stainless Steel Sterilization Trammels-Stainless Steel Storage Containers- Kidney Tray
Holder and Seperator Accessories	Holder and Seperator Accessories for Sterilization Containers
Clogs	Hospital Clogs

**Samsun 26.07.2018**

**Quality System Manager  
Tülay SANCAK**

**General Manager  
Hakan GÜNSELİ**



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