Quality

Bıçakcılar Quality System complies with ISO 9001, EN ISO 13485 and ISO 14001 has been certified by TÜV NORD and TÜV THÜRINGEN. Bıçakcılar products are CE marked. The company globalized as a brand that is relied upon and cared by the world that cares about health.

Bıçakcılar medical equipment and disposable products are produced according to GMP, with latest technologies in modern production facilities established on 26.500 m² land with 30.900 m² closed area. Biocompatible raw materials used in production are in conformity to USP and ISO 10993 Standards. In-house acceptance controls are also performed to meet the stringent demands of our quality system.

Quality Policy

Our quality policy in Bıçakcılar Tıbbi Cihazlar A.Ş. is;

- Innovative thinking is our mandate. Our research and development along with focus on competitiveness, we continuously develop ways of being more productive without any negative impact on quality.
- We fulfill all regulatory and normative requirements (e.g Medical Device Directive and ISO EN 13485 Standard).
- We guarantee compliance for our products as per international standards.
- We make sure that each employee in the organization shares the same mission, vision and strategy so that our corporate culture can only enhance our products and solution for our customers.
- The effectiveness of quality management systems is a top priority for our organisation to meet customer and regulatory requirements.
- We provide the resources for improvement of activities by reviewing the effectiveness of the available quality system and the quality targets which are created in line with the quality policy, on a continuous basis.
- We implement our quality system effectively in every phase of our processes to assure complete customer satisfaction.


CERTIFICATE

TIC

for the management system
according to ISO 9001:2015

The proof of the conforming application with the regulation was furnished and in accordance with certification procedure it is certified for the company

BIÇAKÇILAR TIBBİ CİHAZLAR SAN. VE TİC. A.Ş.
Head Office: Osmangazi Mah. Gazi Cad. No: 21
Esenyurt İstanbul Turkey
Branch: Merkez Mahallesi. Akar Caddesi, Itower No:3 Kat:15
Bomonti Şişli İstanbul Turkey
with branch (see enclosure)

Scope
Customs, foreign trade, manufacturing, logistics, management and administrative organization activities of medical devices and related raw materials and semi-finished products and related sales and service delivery

Certificate Registration No.: TIC 15 100 169655
Valid until: 2022-07-24
Valid from: 2019-07-25

Audit Report No.: 3330 2U38 D0

This certification was conducted in accordance with the TIC auditing and certification procedures and is subject to regular surveillance audits.

TÜV Thüringen e.V.
Certification body for systems and personnel

TÜV THÜRINGEN

Jena, 2019-07-08

IAF DAkkS


TÜV NORD

ZERTIFIKAT / Certificate

DIN EN ISO / EN ISO 13485 : 2016

Hiermit wird bescheinigt, dass die Firma / This certifies, that the company

Bıçakcılar Tıbbi Cihazlar Sanayi ve Ticaret A.Ş.
Osmangazi Mahallesi, Gazi Caddesi No: 21,
Esenyurt 34522 İstanbul
Türkiye

ein Qualitätsmanagementsystem nach der Norm DIN EN ISO 13485 : 2016 / EN ISO 13485 : 2016 - Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke - eingeführt hat und aufrechterhält. Dieses Zertifikat stellt nicht den erforderlichen Nachweis zur Anbringung der CE-Kennzeichnung dar.

has established and maintains a quality management system that meets the requirements of DIN EN ISO 13485 : 2016 / EN ISO 13485 : 2016 - Medical devices - Quality management systems - Requirements for regulatory purposes. This certificate is not an authorization to affix the CE mark.

Geltungsbereich / Scope

Design, Manufacturing, Sterilization and Distribution of Disposable Medical Devices.
Design, Manufacturing and Distribution of Devices for Aspiration, Devices for Vacuum Extraction, Surgical Lights, Examination Lights, Surgical Tables, Orthopedic Traction Systems, Stretchers, Gynecological Tables, Blood Donor Chairs, Eye Surgical Tables, I.V. Stand, Examination Tables.

Reg.-Nr. / Reg.-No. 04 221 980888
Bericht Nr. / Report No. 3529 9434

Gültigkeit / Validity
von / from 2021-09-17
bis / until 2024-09-16
Edition 7

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices
Essen, 2021-09-16

Die Gültigkeit kann unter https://www.tuev-nord.de/de/unternehmen/zertifizierung/zertifikatsdatenbank verifiziert werden.
Validity can be verified at https://www.tuev-nord.de/de/unternehmen/zertifizierung/zertifikatsdatenbank.

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044

DAkkS


TÜV NORD

EG-Zertifikat / EC-Certificate

gem. 93/42/EWG Anhang II ohne (4) / acc. 93/42/EEC Annex II without (4)

Hiermit wird bescheinigt, dass die Firma / This certifies, that the company

Bıçakcılar Tıbbi Cihazlar Sanayi ve Ticaret A.Ş.
Osmangazi Mahallesi, Gazi Caddesi No: 21,
Esenyurt 34522 İstanbul
Türkiye

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Medizinische Einmalartikel und Absauggeräte
Disposable medical devices and devices for aspiration and vacuum extraction

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG eingeführt hat. Zusätzlich zur CE-Kennzeichnung muss die Kennnummer der Benannten Stelle angebracht werden. Das Zertifikat bescheinigt auf Abnahmestichprobe des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Absatz 3. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 3. The certificate may not be transferred under any circumstances.

Reg.-Nr. / Reg.-No. 04 232 980886
Bericht Nr. / Report No. 3524 7139
3526 6209
3526 6290

Gültigkeit / Validity
von / from 2020-04-16
bis / until 2023-09-16
Edition 8

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices
Essen, 2020-04-16

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044

ZLG-BS-236.10.16


TÜV NORD

CERTIFICATE

Management system as per
ISO 14001 : 2015

In accordance with TÜV NORD CERT procedures, it is hereby certified that

BIÇAKCILAR

Bıçakcılar Tıbbi Cihazlar San. ve Tic. A.Ş.
Osmangazi Mah., Gazi Cad., No 21, Esenyurt,
TR-34522 Istanbul,
Turkey

applies a management system in line with the above standard for the following scope

Design, manufacturing and distribution of medical equipment and sterile and non sterile disposable medical products

Certificate Registration No. 44 104 080979
Audit Report No. TR 1286

Valid from 2020-10-14
Valid until 2023-10-13
Initial certification 2008

Certification Body
at TÜV NORD CERT GmbH

Istanbul, 2020-10-14

This certification was conducted in accordance with the TÜV NORD CERT auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.com

IAF DAkkS

Examline 850 Blood Donor Chair

Ref: M2Z 000 0 0



Bıçakcılar Examline 850 Blood Donor Chair is designed and manufactured to provide years of trouble-free service in a variety of applications such as: Blood Banks, Dialysis, Pheresis and Plasma Centers, Hospitals and Clinics.

Ergonomically designed and constructed from the finest materials.

Adjustable armrests provide both patient and operator comfort. A linear actuator motor provides smooth positioning.

The convenient hand pendant, which is easily attached to either side of the head of the chair, controls the motor allowing easy positioning from "head high-foot low" to "head low-foot high" or any suitable position in between.

Technical Details

Seat height:
500 mm
Head height:
1050 - 860 mm
Foot height:
650 - 840 mm
Chair length:
1470 mm
Chair width:
650 mm
Chair width (w/armrest sections):
980 mm
Voltage:
230V, 50/60Hz

Packing Details

Net weight:
52 kg
Gross weight:
92 kg
Packing dimensions:
900 x 1700 x 1160 mm

Positions

Head and foot heights:
Adjustable



Standard Accessories

- Armrests (2 ea)
- Legrest cover (1 ea)





Armrests - Adjustable, detachable
Ref: M2Z 065 4 0 - Right
Ref: M2Z 064 4 0 - Left



Legrest cover
Ref: M2Z 078 5 0

Accessory

- I.V. stand



I.V. stand
Ref: M2Z 100 5 0

Examline 855 Blood Donor Chair

Ref: M2Z 700 0 0



Bıçakcılar Examline 855 Blood Donor Chair is an innovative solution for blood bank, laboratory and hospital use.

Beside blood donation and transfusion applications, Examline 855 is the perfect choice for safe and comfortable transportation of patients.

Examline 855 Blood Donor Chair consists of backrest, seat and leg sections, covered with hygiene and long operation life.

The unique flexible design of Examline 855 Blood Donor Chair is suitable to accommodate patients in both sitting and reclining positions and transferring them between departments without having to lift from the workplace.

The Trendelenburg position and position of backrest section in combination with seat and leg sections are adjusted by a block-lift mechanism operated by means of two steering handles located behind the backrest section.

The headrest can be adjusted to required level in order to provide patient comfort.

The armrests automatically adjust to position of the chair and can be folded up for easy entry of the patient. Armrests have multi-axis and multi-angle motion to enable fixing the patient arm on required position.

The large antistatic casters allow high maneuverability and provide comfort during transportation.

The rear casters have break system and free-motion. Straight positioned front casters and steering handles located on direction of Examline 855 Blood Donor Chair.

Technical Details

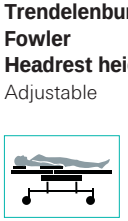
Seat height: 570 mm
Chair horizontal length: 1850 mm
Chair base: 670 x 960 mm
Headrest: 285 x 250 mm
Backrest section: 530 x 890 mm
Seat section: 530 x 540 mm
Leg section: 510 x 440 mm
Arm boards: 120 x 450 mm

Packing Details

Net weight: 63.5 kg
Gross weight: 104 kg
Packing dimensions: 1000 x 1680 x 1100 mm

Positions

Backrest section: Upward 20° - 90° from horizontal
Leg section: Upward 0° - 90° from horizontal
Trendelenburg: 14°
Fowler
Headrest height: Adjustable















Examline 740 Gynecological Examination Table

Ref: M2S 300 0 0





With Optional Foot support

Bıçakcılar Examline 740 Gynecological Examination Table is designed for gynecological, rectoscopy/proctology, urology and urodynamic examinations, minor surgical procedures and obstetric deliveries. With a soft-touch ergonomic design. Examline 740 is constructed with high quality materials providing effective and long operating life in hospitals and clinics.

Gynecological Examination Table consists of backrest and seat sections. Seat extension pads are offered as optional accessory. As standard accessory either foot supports or knee crutches integrated with handles can be selected according to customers' need.

All surfaces contacting with the patient are covered with hygienic polyurethane pads. Antistatic pads are waterproof and easy to clean.

Below listed tabletop positions of Examline 740 can be adjusted with remote control or with multi-functional foot pedals:

- Tabletop height adjustment,
- Trendelenburg/reverse Trendelenburg positions,
- Backrest section forward and backward movements,
- Handle integrated foot supports and knee crutches up and down movements.

Three positions can be preset in memory by use of the remote control unit. All positions are adjusted by electrically operated pistons. Gynecological Examination Table is equipped with battery recharge system. Movements of the table are fed from the battery circuit. Battery power has 30 minutes operating time (approx 30 full positioning).

Electrically adjustable foot supports and a low starting position (600 mm mounting height with 5° reverse Trendelenburg position) offer maximum comfort. The patient can take her place easily - without the need of foot step.

An examination tissue paper dispenser is stored under the backrest section.

A stainless steel waste tray is located below the seat section.

Examline 740 is available in blue color.

Technical Details

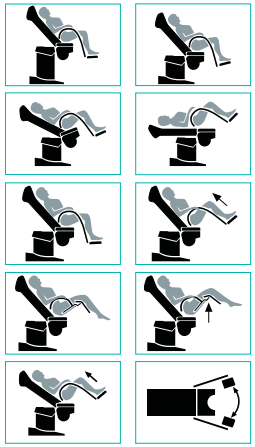
Height adjustment:
660 - 910 mm
Tabletop: 550 x 1270 mm
Table base:
600 x 1085 mm
Head section:
550 x 320 mm
Backrest section:
550 x 600 mm
Seat section:
550 x 385 mm
Length of seat section w/seat extension pad:
550 x 550 mm
Voltage:
230V, 50/60Hz

Packing Details

Net weight (w/o accessories):
180 kg
Gross weight (w/o accessories):
225 kg
Packing dimensions:
1000 x 1680 x 1100 mm

Positions

Backrest section:
52° upward from horizontal position
Seat section:
In combination with backrest section, 19° Trendelenburg and 5° reverse Trendelenburg (providing 600 mm mounting height)
Foot supports:
Integrated with handles, can be swiveled to the sides, and moved up and down (to 140 mm from the floor)
Knee crutches:
Integrated with handles, can be swiveled to the sides, and moved up and down.



Accessories For Examline 740 Gynecological Examination Table

Standard Accessories

- Knee crutches (2 ea)
- Waste tray (1 ea)
- Examination tissue paper (1 ea)



Knee crutches
Ref: M2S 325 5 0 (Ref of 1 ea)



Waste tray
Ref: M2S 171 1 0



Examination tissue paper
Ref: MT1 06 0001

Accessories

- Foot support
- Anaesthetist's frame
- I.V. stand
- Arm boards
- Seat extension pad
- Leg section
- Examination light (Luxline 45 LED)
- Physician stool
- Physician stool w/foot control
- Physician chair
- Physician chair w/foot control



Foot support
Ref: M2S 335 5 0 (Ref of 1 pair)



Anaesthetist's frame
Ref: M3S 000 0 0



I.V. stand
Ref: M3T 000 0 0



Armboards
Ref: M9F 200 0 0 (Ref of 1 ea)



Seat extension pads
Ref: M2S 340 0 0 (Ref of 1 pair)



Leg sections
Ref: M2S 360 0 0 (Ref of 1 pair)



Examination light (Luxline 45 LED)
Ref: M1V 550 0 0



Physician stool
Ref: M0B 000 0 0



Physician stool w/foot control
Ref: M0B 200 0 0



Physician chair
Ref: M0B 100 0 0



Physician chair w/foot control
Ref: M0B 300 0 0