BIÇAKCILAR
TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.

10.07.2023

Manufacturer's Declaration of Certificate Validity:

With respect to the validity of the certificates issued under Council Directive 93/42/EEC on medical devices that have been extended as a result of the REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in-vitro diagnostic medical devices.

Manufacturer Name	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş.
Manufacturer Address	OSMANGAZI MAH. GAZI CAD. NO:21 34522 Istanbul Turkey
SRN Number (Optional)	TR-MF-000022603

EXISTING NOTIFIED BODY DETAILS (MDD)

Name of Notified Body	TÜV NORD CERT GmbH
Address of Notified Body	Am TÜV 1, 45307 Essen, Germany
Notified Body Number	0044
Certificate Number	04 232 980886
Certificate Validity Date	16.09.2023

NOTIFIED BODY DETAILS (which a written agreement has been signed for MDR)

Name of Notified Body	TÜV NORD CERT GmbH
Address of Notified Body	Am TÜV 1, 45307 Essen, Germany
Notified Body Number	0044

This declaration confirms that the devices listed in the attachment meet following conditions for extension of their certificates issued under Council Directive 93/42/EEC (MDD) on medical devices as stated in the regulation 2023/607:

- The certificate covering the listed devices was valid on the 26 May 2021.
- The devices continue to comply with Directive 93/42/EEC (MDD).
- There are no significant changes in the design and intended purpose since 26 May 2021.
- The devices do not present unacceptable risks to health or safety of the patients, users or other persons or to other aspects of the protection of public health.
- A quality management system in accordance with article 10(9), Regulation 2017/745 (MDR) has been put in place by the manufacturer.
- A formal application to the notified body in accordance with section 4.3, first subparagraph of Annex VII Regulation 2017/745 (MDR) for conformity assessment has been made for the devices listed and a signed written agreement is in place in accordance with section 4.3,

Digitally signed by Cojocaru Vera
Date: 2025.11.05 13:41:58 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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first subparagraph of Annex VII Regulation 2017/745 (MDR) before the expiry date of the listed certificate.

- Post market surveillance, market surveillance, vigilance, registration of economic operators and of devices in accordance with Regulation 2017/745 (MDR) is in place for the devices listed.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Signed for and on behalf of the manufacturer:

Manufacturer name: BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş.

Aysel Yıldırım

Quality and Regulatory Executive

Doğan Arpaçay

Operations Director

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TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.

Device list

Device name	Device classification	MDR transition extension date
Pressure Monitoring Set	Class IIb	31 December 2028
Leukocyte Filter Set	Class IIb	31 December 2028
Gamma Leukocyte Filter Set	Class IIb	31 December 2028
Thoracenthesis Set	Class IIa	31 December 2028
Thoracic Catheter	Class IIa	31 December 2028
Arterial Needle	Class IIa	31 December 2028
Endotracheal Tube	Class IIa	31 December 2028
Reinforced Endotracheal Tube	Class IIa	31 December 2028
RAE Endotracheal Tube	Class IIa	31 December 2028
Nasogastric Catheter	Class IIa	31 December 2028
Stomach Catheter	Class IIa	31 December 2028
Feeding Catheter	Class IIa	31 December 2028
Manifold / Manifold Pressure	Class IIa	31 December 2028
Three -Way Stopcock	Class IIa	31 December 2028
Tourniquet Set	Class IIa	31 December 2028
IV Cannula	Class IIa	31 December 2028
Suction Catheter	Class IIa	31 December 2028
Microaggregate Filter Set (Blood Filter Set)	Class IIa	31 December 2028
Soft Drain	Class IIa	31 December 2028
Oxygen Catheter	Class IIa	31 December 2028
Nasal Oxygen Cannula	Class IIa	31 December 2028
Oxygen Connecting Tube	Class IIa	31 December 2028
Tracheostomy Tube	Class IIa	31 December 2028
Extracorporeal PVC Tubing	Class IIa	31 December 2028
Extracorporeal Tubing Set	Class IIa	31 December 2028
Quick Prime Set	Class IIa	31 December 2028
Cardioplegia Set	Class IIa	31 December 2028
Wound Drainage Set	Class IIa	31 December 2028
Infusion Pump Set	Class IIa	31 December 2028
Yankauer Suction Set	Class IIa	31 December 2028
Suction Connecting Tube	Class IIa	31 December 2028
Surgical Braided Tape	Class IIa	31 December 2028
Nelaton Catheter	Class IIa	31 December 2028
Tiemann Catheter	Class IIa	31 December 2028
Hydrophilic coated uretheral Catheter	Class IIa	31 December 2028
IV Filter Set	Class IIa	31 December 2028
Aspirators	Class IIa	31 December 2028
Blood Transfusion Set	Class IIa	31 December 2028
Rectal Catheter	Class IIa	31 December 2028
Umbilical Catheter	Class IIa	31 December 2028
Angiographic Kit	Class IIa	31 December 2028
B -Soft Kit	Class IIa	31 December 2028
Aortic Punch	Class IIa	31 December 2028
Gas Sampling Line	Class IIa	31 December 2028
External Drainage Set	Class IIa	31 December 2028
Vent Catheter	Class IIa	31 December 2028
Vessel Cannula	Class IIa	31 December 2028
Coronary Artery Retraction Clips	Class IIa	31 December 2028
Urine Collection Bag	Class Is	31 December 2028
Pleural Drainage Set	Class Is	31 December 2028
Central Venous Pressure Set	Class Is	31 December 2028
Guedel Airway	Class Is	31 December 2028

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Device name	Device classification	MDR transition extension date
Spigot	Class Is	31 December 2028
Extension Lines	Class Is	31 December 2028
Kapkon Connector	Class Is	31 December 2028
Straight Connector	Class Is	31 December 2028
Straight Luer Connector	Class Is	31 December 2028
Y Connector	Class Is	31 December 2028
Y Luer Connector	Class Is	31 December 2028
Stopper	Class Is	31 December 2028
Instopper	Class Is	31 December 2028
Umbilical Cord Clamp	Class Is	31 December 2028
T.U.R. Set /Arthroscopy set	Class Is	31 December 2028
Transfer Set	Class Is	31 December 2028
Intravenous Infusion Sets	Class Is	31 December 2028
Intravenous Infusion Sets / Flowmeter	Class Is	31 December 2028
Intravenous Infusion Sets / Burette	Class Is	31 December 2028
B -Safe	Class Is	31 December 2028
Intubation Stylet	Class Is	31 December 2028
Combi Stopper	Class Is	31 December 2028
Urimeter	Class Is	31 December 2028
Thoracic Drainage Set	Class Is	31 December 2028
Vaginal Specula	Class Is	31 December 2028
ENEMA Set	Class Is	31 December 2028
I.V. Infusion Set w/B-Flow Flow Regulator	Class Is	31 December 2028
Control Syringe	Class Is	31 December 2028
Meconium Aspiration Connector	Class Is	31 December 2028
Urimeter	Class Im	31 December 2028
C.V.P. Set	Class Im	31 December 2028
Pleural Drainage Set	Class Im	31 December 2028
Volumetric Exerciser (B -Spiro)	Class Im	31 December 2028
Infusion Set w/Burette	Class Im	31 December 2028
Thoracic Drainage Set	Class Im	31 December 2028

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