Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **Comerț-Magor S.R.L.**, cu sediul în **Moldova, mun. Chișinău MD2004, str. Bucuriei 1**, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivelor medicale:

Numarul de catalog	Denumire	Modelul	Tip dispozitiv	Clasa de risc	Cod GMDN	Producator
330 0321 1	Adaptor cardioplegic de tip Y	Duo	CARDIOPLEGIA ADAPTER - DUO	Class-IIa	58824	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş
330 0322 1	Adaptor cardioplegic de tip Y	DUO, W/VENT LINE	CARDIOPLEGIA ADAPTER - DUO, W/VENT LINE	Class-IIa	58824	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş
330 0460 1	Canule pentru perfuzia coronariană	10CH-45DEG.TIP	CORONARY ARTERY PERFUSION CANNULA 10CH-45DEG.TIP	Class-III	34914	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş
330 0461 1	Canule pentru perfuzia coronariană	12CH-45DEG.TIP	CORONARY ARTERY PERFUSION CANNULA 12CH-45DEG.TIP	Class-III	34914	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş
330 0462 1	Canule pentru perfuzia coronariană	14CH-45DEG.TIP	CORONARY ARTERY PERFUSION CANNULA 14CH-45DEG.TIP	Class-III	34914	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş
330 0465 1	Canule pentru perfuzia coronariană	10CH-90DEG.TIP	CORONARY ARTERY PERFUSION CANNULA 10CH-90DEG.TIP	Class-III	34914	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş
330 0466 1	Canule pentru perfuzia coronariană	12CH-90DEG.TIP	CORONARY ARTERY PERFUSION CANNULA 12CH-90DEG.TIP	Class-III	34914	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş
330 0467 1	Canule pentru perfuzia coronariană	14CH-90DEG.TIP	CORONARY ARTERY PERFUSION CANNULA 14CH-90DEG.TIP	Class-III	34914	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş

Sunt autentice și corespund realității.

Administrator Cojocaru Vladimir *Semnătura* _____

Data 30.09.2023

Digitally signed by Cojocaru Vera
Date: 2023.09.30 18:19:52 EEST
Reason: MoldSign Signature
Location: Moldova

Anexă

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. **33** din **30.09.2023**

Solicitantul **Comerț-Magor S.R.L.**, cu sediul **Moldova, mun. Chișinău MD2004, str. Bucuriei 1**, tel./fax: **022742200/022743931**, e-mail **veracojocaru@mail.ru**, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Numarul de catalog	Denumire	Modelul	Tip dispozitiv	Clasa de risc	Cod GMDN	Producator
330 0321 1	Adaptor cardioplegic de tip Y	Duo	CARDIOPLEGIA ADAPTER - DUO	Class-IIa	58824	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş
330 0322 1	Adaptor cardioplegic de tip Y	DUO, W/VENT LINE	CARDIOPLEGIA ADAPTER - DUO, W/VENT LINE	Class-IIa	58824	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş
330 0460 1	Canule pentru perfuzia coronariană	10CH-45DEG.TIP	CORONARY ARTERY PERFUSION CANNULA 10CH-45DEG.TIP	Class-III	34914	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş
330 0461 1	Canule pentru perfuzia coronariană	12CH-45DEG.TIP	CORONARY ARTERY PERFUSION CANNULA 12CH-45DEG.TIP	Class-III	34914	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş
330 0462 1	Canule pentru perfuzia coronariană	14CH-45DEG.TIP	CORONARY ARTERY PERFUSION CANNULA 14CH-45DEG.TIP	Class-III	34914	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş
330 0465 1	Canule pentru perfuzia coronariană	10CH-90DEG.TIP	CORONARY ARTERY PERFUSION CANNULA 10CH-90DEG.TIP	Class-III	34914	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş
330 0466 1	Canule pentru perfuzia coronariană	12CH-90DEG.TIP	CORONARY ARTERY PERFUSION CANNULA 12CH-90DEG.TIP	Class-III	34914	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş
330 0467 1	Canule pentru perfuzia coronariană	14CH-90DEG.TIP	CORONARY ARTERY PERFUSION CANNULA 14CH-90DEG.TIP	Class-III	34914	BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş

Se anexează următoarele acte:

a) declarația de conformitate CE emisă de producător pentru dispozitivele fabricate
b) certificatul de conformitate CE valabil pentru dispozitivele fabricate
c) actul prin care producătorul își desemnează reprezentantul

Data **30.09.2023** Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

BIÇAKCILAR
TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.

POWER OF ATTORNEY

The Company Bicakcilar Tibbi Cihazlar Sanayi ve Ticaret A.S.., located at Osmangazi Mahallesi, Gazi Caddesi No:21, Esenyurt 34522, Istanbul, Turkey hereinafter called - «The Manufacturer», duly represented by Sr. International Sales Manager Mirlind Bunjaku, acting under and by virtue of the Articles of Association.

By this power of attorney authorizes:

The Company **"Comert-Magor" S.R.L.,** Registration number: 1003600022518 located at str. Bucuriei 1, mun. Chisinau, MD-2004, Moldova, hereinafter called - «An authorized representative of the manufacturer».

-To represent the interests of The Manufacturer on the circulation of medical devices produced by Bicakcilar Tibbi Cihazlar Sanayi ve Ticaret A.S., on the territory of the Republic of Moldova.

- To register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.;

- To conduct negotiations;

- To sign the statements, applications, contracts and other necessary documents, including financial, with the purpose of state registration and conformity assessment of medical devices;

- To provide with technical, operational and other documentation and materials required for the state registration and conformity assessment of the medical device, to give clarifying explanation;

- To initiate changes to the registration certificate for medical devices, if it is necessary;

- To provide with other necessary information and documents for the state registration and conformity assessment of medical device;
- To make payments for the services;

- To perform other necessary actions related to the registration or conformity assessment of the medical device;

- To get the Registration certificate issued in the name of **Bicakcilar Tibbi Cihazlar Sanayi ve Ticaret A.S.**

This power of attorney is granted for **3 years**, with a right of substitution.

BIÇAKCILAR
TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.

Name: Mehmet Mahmutoglu
Title: International Sales Manager

BIÇAKCILAR
TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.

Name: Mirlind Bunjaku
Title: Sr. International Sales Manager

Osmangazi Mah. Gazi Cad. No:21
Esenyurt 34522 İstanbul, Turkey
T: +90 (212) 689 02 20
F: +90 (212) 689 02 29
factory@bicakcilar.com
www.bicakcilar.com

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 anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. 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 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / *Reg.-No.* 04 232 980886
Bericht Nr. / *Report No.* 3524 7139
3526 6208
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*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIb
Products of class IIb

Pressure Monitoring Set
Leukocyte Filter Set
Gamma Leukocyte Filter Set

Produkte der Klasse IIa
Products of class IIa

Thoracenthesis Set
Thoracic Catheter
Arterial Needle
Endotracheal Tube
Reinforced Endotracheal Tube
RAE Endotracheal Tube
Nasogastric Catheter
Stomach Catheter
Feeding Catheter
Manifold / Manifold Pressure
Three-Way Stopcock

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-25

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*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIa
Products of class IIa

Tourniquet Set
IV Cannula
Suction Catheter
Microaggregate Filter Set (Blood Filter Set)
Soft Drain
Oxygen Catheter
Nasal Oxygen Cannula
Oxygen Connecting Tube
Tracheostomy Tube
Extracorporeal PVC Tubing
Extracorporeal Tubing Set
Quick Prime Set
Cardioplegia Set
Wound Drainage Set
Infusion Pump Set
Yankauer Suction Set
Suction Connecting Tube
Surgical Braided Tape
Nelaton Catheter
Tiemann Catheter

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
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ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIa
Products of class IIa

Hydrophilic coated uretheral Catheter
IV Filter Set
Aspirators
Blood Transfusion Set
Rectal Catheter
Umbilical Catheter
Angiographic Kit
B-Soft Kit
Aortic Punch
Gas Sampling Line
External Drainage Set
Vent Catheter
Vessel Cannula
Coronary Artery Retraction Clips

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

Zertifizierungsstelle für Medizinprodukte
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Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

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ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Is (steril)
Products of class Is (sterile)

Urine Collection Bag
Pleural Drainage Set
Central Venous Pressure Set
Guedel Airway
Spigot
Extension Lines
Kapkon Connector
Straight Connector
Straight Luer Connector
Y Connector
Y Luer Connector
Stopper
Instopper
Umbilical Cord Clamp
T.U.R. Set / Arthroscopy set
Transfer Set
Intravenous Infusion Sets
Intravenous Infusion Sets / Flowmeter
Intravenous Infusion Sets / Burette

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
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Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

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ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Is (steril)
Products of class Is (sterile)

B-Safe
Intubation Stylet
Combi Stopper
Urimeter
Thoracic Drainage Set
Vaginal Specula
ENEMA Set
I.V. Infusion Set w/B-Flow Flow Regulator
Control Syringe
Meconium Aspiration Connector

Anmerkung: Für Produkte der Klasse I steril beschränkt sich das Zertifizierungsverfahren auf die Aspekte der Herstellungsschritte in Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität.
Note: *For products of class I sterile the certification process is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.*

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-25

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*

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Im (mit Messfunktion)
Products of class Im (with measuring function)

Urimeter
C.V.P. Set
Pleural Drainage Set
Volumetric Exerciser (B-Spiro)
Infusion Set w/Burette
Thoracic Drainage Set

Anmerkung: Für Produkte der Klasse I mit Messfunktion beschränkt sich das Zertifizierungsverfahren auf die Herstellungsschritte in Zusammenhang mit der Konformität der Produkte mit den messtechnischen Anforderungen.
Note: *For products of class I with measuring functions the certification process is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.*

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-25

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*

Benannt durch/Designated by
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www.zlg.de
ZLG-BS-236.10.16

TÜVNORD

TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany

BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş.
Osmangazi Mahallesi, Gazi Caddesi No: 21,
Esenyurt 34522 İstanbul
Turkey

TÜV NORD CERT GmbH
Am TÜV 1
45307 Essen
Germany

Phone: +49 201 825 2236

medical@tuev-nord.de
tuev-nord-cert.com/en

TÜV®

Reference	Contact	Direct Dial	Date
No.: 8003060047	E-Mail: medical@tuev-nord.de	Tel.: +49 201 825 2236	29 June 2023

Notified Body Confirmation Letter
Reference: 8003060047

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, TÜV NORD CERT GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0044 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

BIÇAKCILAR TIBBI CIHAZLAR SAN. VE TIC. A.Ş.
Osmangazi Mahallesi, Gazi Caddesi No: 21,
Esenyurt 34522 İstanbul
Turkey
SRN Number: TR-MF-000022603

TÜVNORD

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

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)

On behalf of the Notified Body,

TÜVNORD i. V. Digital unterschrieben von Mühlenberg Kevin Datum: 2023.07.05 09:16:27 +02'00'

i. V. Kevin Mühlenberg
Head of Projectmanagement
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD i. A. Digital unterschrieben von Mestmacher Bodo Datum: 2023.07.05 09:08:26 +02'00'

i. A. Bodo Mestmacher
Specialist Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Pressure Monitoring Set	Class IIb	N/A	04232980886
Leukocyte Filter Set	Class IIb	N/A	04232980886
Gamma Leukocyte Filter Set	Class IIb	N/A	04232980886
Thoracenthesis Set	Class IIa	N/A	04232980886
Thoracic Catheter	Class IIa	N/A	04232980886
Arterial Needle	Class IIa	N/A	04232980886
Endotracheal Tube	Class IIa	N/A	04232980886
Reinforced Endotracheal Tube	Class IIa	N/A	04232980886
RAE Endotracheal Tube	Class IIa	N/A	04232980886
Nasogastric Catheter	Class IIa	N/A	04232980886
Stomach Catheter	Class IIa	N/A	04232980886
Feeding Catheter	Class IIa	N/A	04232980886
Manifold / Manifold Pressure	Class IIa	N/A	04232980886
Three -Way Stopcock	Class IIa	N/A	04232980886
Tourniquet Set	Class IIa	N/A	04232980886
IV Cannula	Class IIa	N/A	04232980886
Suction Catheter	Class IIa	N/A	04232980886
Microaggregate Filter Set (Blood Filter Set)	Class IIa	N/A	04232980886
Soft Drain	Class IIa	N/A	04232980886
Oxygen Catheter	Class IIa	N/A	04232980886
Nasal Oxygen Cannula	Class IIa	N/A	04232980886
Oxygen Connecting Tube	Class IIa	N/A	04232980886
Tracheostomy Tube	Class IIa	N/A	04232980886
Extracorporeal PVC Tubing	Class IIa	N/A	04232980886
Extracorporeal Tubing Set	Class IIa	N/A	04232980886
Quick Prime Set	Class IIa	N/A	04232980886
Cardioplegia Set	Class IIa	N/A	04232980886
Wound Drainage Set	Class IIa	N/A	04232980886
Infusion Pump Set	Class IIa	N/A	04232980886
Yankauer Suction Set	Class IIa	N/A	04232980886
Suction Connecting Tube	Class IIa	N/A	04232980886
Surgical Braided Tape	Class IIa	N/A	04232980886
Nelaton Catheter	Class IIa	N/A	04232980886
Tiemann Catheter	Class IIa	N/A	04232980886
Hydrophilic coated uretheral Catheter	Class IIa	N/A	04232980886
IV Filter Set	Class IIa	N/A	04232980886
Aspirators	Class IIa	N/A	04232980886
Blood Transfusion Set	Class IIa	N/A	04232980886
Rectal Catheter	Class IIa	N/A	04232980886
Umbilical Catheter	Class IIa	N/A	04232980886
Angiographic Kit	Class IIa	N/A	04232980886

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
B -Soft Kit	Class IIa	N/A	04232980886
Aortic Punch	Class IIa	N/A	04232980886
Gas Sampling Line	Class IIa	N/A	04232980886
External Drainage Set	Class IIa	N/A	04232980886
Vent Catheter	Class IIa	N/A	04232980886
Vessel Cannula	Class IIa	N/A	04232980886
Coronary Artery Retraction Clips	Class IIa	N/A	04232980886
Urine Collection Bag	Class Is	N/A	04232980886
Pleural Drainage Set	Class Is	N/A	04232980886
Central Venous Pressure Set	Class Is	N/A	04232980886
Guedel Airway	Class Is	N/A	04232980886
Spigot	Class Is	N/A	04232980886
Extension Lines	Class Is	N/A	04232980886
Kapkon Connector	Class Is	N/A	04232980886
Straight Connector	Class Is	N/A	04232980886
Straight Luer Connector	Class Is	N/A	04232980886
Y Connector	Class Is	N/A	04232980886
Y Luer Connector	Class Is	N/A	04232980886
Stopper	Class Is	N/A	04232980886
Instopper	Class Is	N/A	04232980886
Umbilical Cord Clamp	Class Is	N/A	04232980886
T.U.R. Set /Arthroscopy set	Class Is	N/A	04232980886
Transfer Set	Class Is	N/A	04232980886
Intravenous Infusion Sets	Class Is	N/A	04232980886
Intravenous Infusion Sets / Flowmeter	Class Is	N/A	04232980886
Intravenous Infusion Sets / Burette	Class Is	N/A	04232980886
B -Safe	Class Is	N/A	04232980886
Intubation Stylet	Class Is	N/A	04232980886
Combi Stopper	Class Is	N/A	04232980886
Urimeter	Class Is	N/A	04232980886
Thoracic Drainage Set	Class Is	N/A	04232980886
Vaginal Specula	Class Is	N/A	04232980886
ENEMA Set	Class Is	N/A	04232980886
I.V. Infusion Set w/B-Flow Flow Regulator	Class Is	N/A	04232980886
Control Syringe	Class Is	N/A	04232980886
Meconium Aspiration Connector	Class Is	N/A	04232980886
Urimeter	Class Im	N/A	04232980886
C.V.P. Set	Class Im	N/A	04232980886
Pleural Drainage Set	Class Im	N/A	04232980886
Volumetric Exerciser (B -Spiro)	Class Im	N/A	04232980886
Infusion Set w/Burette	Class Im	N/A	04232980886
Thoracic Drainage Set	Class Im	N/A	04232980886

TÜVNORD

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-07-05	Rev. 0	Initial issue

BIÇAKCILAR
TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.

UYGUNLUK DEKLARASYONU
DECLARATION OF CONFORMITY
(Sınıf/ Class IIb, IIa, Is, Im)

Doküman Numarası Document Number	DoC-TK2	**Revizyon No:** 34 Revision No	**Tarih:** 07.10.2022 Date
Üretici Firma Manufacturer	BIÇAKCILAR Tıbbi Cihazlar San. Ve Tic. A.Ş.		
Firma adresi Manufacturer Address	Osmangazi Mahallesi Gazi Caddesi No:21 Esenyurt 34522 İSTANBUL/TÜRKİYE		
Onaylanmış Kuruluş & Adresi Notified Body & Address	TÜV NORD CERT GmbH Am TÜV 1 45307 /Essen-Germany		

BIÇAKCILAR Tıbbi Cihazlar San. Ve Tic. A.Ş. Yetkili otorite TÜV NORD CERT GmbH (N° 0044) tarafından değerlendirmiştir.
Bu deklerasyon, Tıbbi Cihaz Direktifi 93/42 EEC Ek VII ve Düzeltme 2007/47/EEC ile uyumlu olarak hazırlanmıştır.

BIÇAKCILAR Tıbbi Cihazlar San. Ve Tic. A.Ş. having been assessed by TÜV NORD CERT GmbH Notified Body N° 0044.
This declaration is made in accordance with Annex VII of the Medical Devices Directive 93/42 EEC and Amendment 2007/47/EEC

Uygunluk deklarasyonunda bulunan bütün ürünler için/For all products which are mentioned in the DoC.

Sertifikalar Certificates	**Sertifika No** Certicate No	**Veriliş Tarihi** Date of Issue	**Son Kullanma Tarihi** Expiry Date
EN ISO 13485 (*)	04 221 980886	27.07.2022	26.05.2024
93/42 EEC Ek II / Annex II (4 hariç /without 4)	04 232 980886	16.04.2020	16.09.2023

(*) EN ISO 13485: 2016 Tıbbi Cihazlar- Kalite Yönetim Sistemleri- Ruhsatlandırma Amaçlı Gereklilikler / Medical Devices-Quality Management Systems- Requirements for Regulatory Purposes

Bıçakcılar Tıbbi Cihazlar A.Ş, Tıbbi Cihazlar Direktifinin 93/42 EEC ve Ek 2007/47/EEC Ek II maddelerine uygun olarak aşağıda belirtilen ürünler için bütün sorumluluğu üstlenir ve ürünün aşağıda belirtilen standardlara ya da diğer düzenleyici mevzuatlara uygunluğunu deklare eder.
Bıçakcılar Tıbbi Cihazlar A.Ş, Declare under our sole responsibility that the products below to which this declaration relates are in conformity with the following standards or other regulatory laws following the provisions of Medical Device Directive 93/42 EEC and Amendment 2007/47/EEC Annex II.

- **ISO 9001: 2015 Kalite Yönetim Sistemleri – Gereklilikler/** Quality Management Systems- Requirements
- **EN ISO 13485: 2016 Tıbbi Cihazlar- Kalite Yönetim Sistemleri – Mevzuat Amaçları Bakımından Şartlar /** Medical Devices- Quality Management Systems-Requirements for Regulatory Purposes
- **EN ISO 14971 Tıbbi cihazlar – Tıbbi cihazlara risk yönetiminin uygulanması** / Medical devices - Application of risk management to medical devices
- **ISO/TR 24971 Tıbbi cihazlar - ISO 14971'in uygulanmasına ilişkin kılavuz /** Medical devices — Guidance on the application of ISO 14971
- **EN ISO 10993 Tıbbi cihazların Biyolojik Değerlendirilmesi /** Biological Evaluation of Medical Devices
- **EN ISO 11135 Sağlık Malzemelerinin Sterilizasyonu-Etilenoksit /** Sterilization of Heathcare products-Ethylene oxide
- **EN ISO 11607 Son Olarak Steril Edilen Tıbbi Cihazlar için Ambalajlama/** Packaging for terminally sterilized medical device

- **EN ISO 11737 Tıbbi Cihazların Sterilizasyonu-Mikrobiyolojik Metodlar** /Sterilization of medical devices -- Microbiological methods

- **ISO 20417 Tıbbi cihazlar - İmalatçı tarafından sağlanacak bilgiler /** Medical devices — Information to be supplied by the manufacturer
- **EN ISO 15223 Tıbbi cihazlar - Tıbbi cihaz etiketlerinde, etiketlemede ve sunulacak bilgide kullanılacak semboller /** Medical devices — Symbols to be used with information to be supplied by the manufacturer
- **EN ISO 11138 Sağlık Bakım Ürünlerinin Sterilizasyonu- Biyolojik İndikatörler /** Sterilization Of Health Care Products - Biological Indicators / Sterilization Of Health Care Products - Biological Indicators
- **EN ISO 14644 Temiz odalar ve bunlarla ilgili kontrollü ortamlar** / Cleanrooms and associated controlled environments
- **ISO/TR 20416 Tıbbî cihazlar - Üreticiler için Pazar Arz Sonrası Gözetim/** Medical devices — Post-market surveillance for manufacturers
- **EN 62366-1 Tıbbi cihazlar - Bölüm 1: Kullanılabilirlik tekniğinin tıbbi cihazlara uygulanması** / Medical devices - Part 1: Application of usability engineering to medical devices
- **IEC 62366-2 Tıbbi cihazlar - Bölüm 2: Kullanılabilirlik tekniğinin tıbbi cihazlara uygulanmasına ilişkin rehberlik /** Medical devices — Part 2: Guidance on the application of usability engineering to medical devices
- **MDCG 2020-6 Eski cihazlar için yeterli klinik kanıt hakkında rehberlik /** Guidance on sufficient clinical evidence for legacy devices
- **MDCG 2021-25 MDR gerekliliklerinin "eski cihazlara" ve 90/385/EEC veya 93/42/EEC Direktifleri uyarınca 26 Mayıs 2021'den önce piyasaya sürülen cihazlara uygulanması /** Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC

Sınıf IIb Ürünler / *Class IIb Products*						
Sıra No *No*	**Ürün Referansı** *Product Reference*	**Ürün Adı** *Product Name*	**GMDN Kodu** GMDN Code	**Sterilite Durumu** Sterility State	**İlgili Ürün Standardı** *Related Product Standard*	**Ürün Risk Kuralı** Device Risk Rule
1	157 00XX 1 015 20XX 1 157 00XX 1G 015 20XX 1G	Lökosit Filtre Seti *Leukocyte Filter Set*	35071	Steril *Sterile*	ANSI/AAMI BF 64:2012	Kural 3 / Rule 3 Kural18 / Rule 18
2	040 XXXX 1 400 XXXX 1	Basınç İzleme Seti *Pressure Monitoring Set*	35529	Steril *Sterile*	ISO 8536-4: 2019 EN 60601-1:2006/A1:2013 EN 60601-2-34: 2014	Kural 10 Rule 10

Sınıf IIa Ürünler / *Class IIa Products*						
Sıra No *No*	**Ürün Referansı** *Product Reference*	**Ürün Adı** *Product Name*	**GMDN Kodu** GMDN Code	**Sterilite Durumu** Sterility State	**İlgili Ürün Standardı** *Related Product Standard*	**Ürün Risk Kuralı** Device Risk Rule
1	015 0102 1	Arteriyal İğne *Arterial Needle*	12747	Steril *Sterile*	EN ISO 80369-7 (2016)	Kural 6 Rule 6
2	104 1001 1 010 2XXX 1	Infüzyon pompa seti *Infusion pump set*	35833	Steril *Sterile*	ISO 8536-4 (2019) EN ISO 8536-8 (2015)	Kural 2 Rule 2

3	113 XXXX 1 114 XXXX 1	IV Filtre Seti *IV Filter Set*	35072	Steril *Sterile*	ISO 8536-4 (2019) ISO 80369-7 (2016)	Kural 3 Rule 3
4	115 0101 1	Eksternal Drenaj Büret- 150ml *External Drainage Burette-150ml*	61796	Steril *Sterile*	ISO 8536-5 (2004) ISO 20697 (2018)	Kural 2 Rule 2
5	115 0111 1	Eksternal Drenaj Büret-150ml Plakalı *External Drainage Burette-150ml - W/plate*	61796	Steril *Sterile*	ISO 8536-5 (2004) ISO 20697 (2018)	Kural 2 Rule 2
6	123 1XXX 1	Üç yollu musluklu uzatma *Extention Line w/ Three way Stopcock*	12170	Steril *Sterile*	ISO 80369-7 (2016) ISO 8536-9 (2015)	Kural 2 Rule 2
7	145 XXXX 1 146 XXXX 1 014 XXXX 1 095 10XX 1	B-CAT I.V Kanül *B-CAT I.V Cannula*	34905	Steril *Sterile*	EN ISO 10555-1 (2013-A1:2018) EN ISO 10555-5 (2013) ISO 80369-7 (2016)	Kural 7 Rule 7
8	150 XXXX 1 151 XXXX 1 154 XXXX 1 155 XXXX 1 015 00XX 1 095 12XX 1	Kan Transfüzyon Seti *Blood Transfusion Set*	38569	Steril *Sterile*	ISO 80369-7 (2016) ISO 1135-4 (2015)	Kural 2 Rule 2
9	155 XXXX 1 156 XXXX 1	Mikroagregat Filtre Seti *Microaggregate Filter Set*	35071	Steril *Sterile*	ISO 1135-4 (2015)	Kural 3 Rule 3
10	160 XXXX 1 161 XXXX 1 016 XXXX 1	Yankauer Aspirasyon Ucu *Yankauer Suction Handle*	35917	Steril *Sterile*	NA	Kural 6 Rule 6
11	162 XXXX 1	Aspiratör ucu *Suction wand*	35917	Steril *Sterile*	NA	Kural 6 Rule 6
12	164 XXXX 1 165 XXXX 1 166 XXXX 1 167 XXXX 1 168 XXXX 1	Yankauer Aspirasyon Seti *Yankauer Suction Set*	35917	Steril *Sterile*	ISO 20697 (2018) ISO 8836 (2019)	Kural 6 Rule 6
13	168 XXXX X 169 XXXX 1	Aspirasyon Bağlantı Hortumu *Suction Connecting Tube*	16779	Steril *Sterile*	ISO 20697 (2018)	Kural 6 Rule 6
14	173 XXXX 1 017 XXXX 1 171 XXXX 1	B-Vak Doku Drenaj Seti B-Vak Mini Doku Drenaj Seti *B-Vak Wound Drainage Set* *B-Vak Mini Wound Drainage Set*	35824	Steril *Sterile*	ISO 20697 (2018)	Kural 7 Rule 7
15	017 11XX 1	Redon Dren-Trokar *Redon Drain-Trochar*	11305	Steril *Sterile*	ISO 20697 (2018)	Kural 7 Rule 7

16	180 XXXX 1 182 XXXX 1	Toraks Kateteri – Genişleyen Uçlu *Thoracic Catheter w/Flared End*	47796	Steril *Sterile*	ISO 20697 (2018)	Kural 7 Rule 7
17	181 XX01 1 183 XX01 1	Toraks Kateteri – Tut Çek Konnektörlü Uç *Thoracic Catheter w/Pull Through End*	47796	Steril *Sterile*	ISO 20697 (2018)	Kural 7 Rule 7
18	184 XXXX 1	Toraks Kateteri Trokarlı *Thoracic Catheter w/Throcar*	47796	Steril *Sterile*	ISO 20697 (2018)	Kural 7 Rule 7
19	189 XXXX 1 019 XXXX 1	Aspirasyon Kateteri (Kapkon Konnektörlü) *Suction Catheter (w/Kapkon connector)*	34923	Steril *Sterile*	ISO 8836 (2019)	Kural 5 Rule 5
20	190 XXXX 1 191 XX17 1 019 XXXX 1	Aspirasyon Kateteri *Suction Catheter*	34923	Steril *Sterile*	ISO 8836 (2019)	Kural 5 Rule 5
21	191 XX11 1 019 XXXX 1	Aspirasyon Kateteri-Vakum Kontrollü *Suction Catheter w/Vacuum Control Connector*	34923	Steril *Sterile*	ISO 8836 (2019)	Kural 5 Rule 5
22	019 535X 1	Aspirasyon Kateteri Vakum Kontrollü Konnektör Kesik Uç Delikli *Suction Catheter, w/Vacuum Control Connector Beveled Tip w/Hole*	34923	Steril *Sterile*	ISO 8836 (2019)	Kural 5 Rule 5
23	190 XXXX 1 191 XXXX 1 019 XXXX 1	Aspirasyon Kateteri- Kılıflı Aspirasyon Kateteri- Kılıflı, Eğimli Uç Aspirasyon Kateteri-Vakum Kontrollü *Sleeved Suction Catheter* *Sleeved Suction Catheter,* *Beveled Tip* *Suction Catheter w/Vacuum Control Connector*	34923	Steril *Sterile*	ISO 8836 (2019)	Kural 5 Rule 5
24	193 XXXX 1 019 XXXX 1	Mide Kateteri *Stomach Catheter*	35415	Steril *Sterile*	NA	Kural 5 Rule 5
25	194 XXXX 1 019 XXXX 1	Nazogastrik Kateter *Nasogastric Catheter*	14221	Steril *Sterile*	NA	Kural 5 Rule 5
26	195 XX01 1 195 XX05 1 019 XXXX 1	Nelaton Kateter Nelaton Female Kateter *Nelaton Catheter* *Nelaton Female Catheter*	36125	Steril *Sterile*	ISO 20696 (2018)	Kural 5 Rule 5
27	195 XX20 1 019 XXXX 1	Tiemann Kateteri *Tiemann Catheter*	36125	Steril *Sterile*	ISO 20696 (2018)	Kural 5 Rule 5

28	196 XXXX 1	B-Soft Hidrofilik Kaplı Kateter *B-Soft Hydrophilic Coated Catheter*	36125	Steril *Sterile*	ISO 20696 (2018)	Kural 5 Rule 5
29	196 XX21 1	B-SOFT Kit	36125	Steril *Sterile*	ISO 20696 (2018)	Kural 5 Rule 5
30	197 XXXX 1 019 XXXX 1	Beslenme Kateteri *Feeding Catheter*	14221	Steril *Sterile*	NA	Kural 5 Rule 5
31	197 XX21 1	Beslenme Kateteri- Enfit Konnektörlü *Feeding Catheter- w/ Enfit Connector*	14221	Steril *Sterile*	ISO 20695 (2020)	Kural 5 Rule 5
32	198 XXXX 1 019 XXXX 1	Göbek Kateteri *Umbilical Catheter*	10759	Steril *Sterile*	ISO 80369-7 (2016) EN ISO 10555-1 (2013-A1:2018)	Kural 7 Rule 7
33	199 XXXX 1 019 XXXX 1	Rektal Kateter *Rectal Catheter*	46202	Steril *Sterile*	EN 12439 (1999)	Kural 5 Rule 5
34	300 XXXX 1 304 XXXX 1 310 XXXX 1 311 XXXX 1 312 XXXX 1 315 XXXX 1 776 4001 1 030 XXXX 1 032 XXXX 1	Ekstrakorporeal Tüp Set *Extracorporeal Tubing Set*	35441	Steril *Sterile*	ISO 15676 (2016) ISO 80369-7 (2016)	Kural 2 Rule 2
35	305 XXXX X 306 XXXX X 307 XXXX X 030 XXXX 1	Ekstrakorporeal PVC Hortum *Extracorporeal PVC Tubing*	46721	Steril *Sterile*	ISO 15676 (2016)	Kural 2 Rule 2
36	320 XXXX 1 032 XXXX 1	Hızlı Doldurma Seti *Quick Prime Set*	35441	Steril *Sterile*	ISO 15676 (2016)	Kural 2 Rule 2
37	323 XXXX 1	Y Adaptör / Perfüzyon Y-Adaptör *Y Adapter / Perfusion Y-Adapter*	58824	Steril *Sterile*	NA	Kural 2 Rule 2
38	325 XXXX 1 032 XXXX 1	Kardiopleji Set *Cardioplegia Set*	16163	Steril *Sterile*	ISO 80369-7 (2016) ISO 1135-4 (2015)	Kural 2 Rule 2
39	330 0XXX 1	Vent Kateter *Vent Catheter*	17613	Steril *Sterile*	ISO 20697 (2018) ISO 80369-7 (2016)	Kural 7 Rule 7
40	330 02XX 1	Vessel Kanül *Vessel Cannula*	47798	Steril *Sterile*	ISO 80369-7 (2016)	Kural 7 Rule 7
41	330 03XX 1	Kardiyopleji Adaptörü *Cardioplegia Adapter*	58824	Steril *Sterile*	NA	Kural 2 Rule 2
42	330 05XX 1 330 0XXX 1	Turnike set *Tourniquet set*	36082	Steril *Sterile*	NA	Kural 7 Rule 7

43	332 XXXX 1	Aortik Punch *Aortic Punch*	47914	Steril *Sterile*	NA	Kural 6 Rule 6
44	135 XXXX 1 138 XXXX 1 340 XXXX 1 341 XXXX 1	Anjiografik Opak Madde Verme Seti *Angiographic Kit*	16545	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
45	420 XX01 1 042 000X 1	Yumuşak Dren *Soft Drain*	11305	Steril *Sterile*	ISO 20697 (2018)	Kural 7 Rule 7
46	421 0001 1	Torasentez Seti *Thoracentesis Set*	10817	Steril *Sterile*	ISO 80369-7 (2016) EN ISO 8669-2 (1996)	Kural 6 Rule 6
47	425 0001 1 042 0001 1	Göğüs Drenaj Torbası *Pleural Drainage Bag*	10817	Steril *Sterile*	NA	Kural 7 Rule 7
48	440 4001 1	Arteriyal Filtre Seti *Arterial Filter Set*	33309	Steril *Sterile*	NA	Kural 2 Rule 2
49	550 00XX 1 551 00XX 1 055 XXXX 1	Endotrakeal Tüp (Balonlu/Balonsuz) *Endotracheal Tube (Cuffed/Uncuffed)*	46967	Steril *Sterile*	EN ISO 5361 (2016)	Kural 5 Rule 5
50	550 8XXX 1 551 8XXX 1	RAE Endotrakeal Tüp (Balonlu/Balonsuz) *RAE Endotracheal Tube (Cuffed/Uncuffed)*	46967	Steril *Sterile*	EN ISO 5361 (2016)	Kural 5 Rule 5
51	550 7XXX 1 551 7XXX 1 055 XXXX 1 095 22XX 1	Spiralli Endotrakeal Tüp (Balonlu/Balonsuz) *Reinforced Endotracheal Tube (Cuffed/Uncuffed)*	46569	Steril *Sterile*	EN ISO 5361 (2016)	Kural 5 Rule 5
52	551 1XXX 1	Endotrakeal Tüp (Balonlu, XX mm Stile) Endotracheal Tube *(Cuffed with XX mm Stylet)*	46967	Steril *Sterile*	EN ISO 5361 (2016)	Kural 5 Rule 5
53	551 20XX 1	Spiralli Endotrakeal Tüp (Balonlu, XX mm Stile) *Reinforced Endotracheal Tube (Cuffed with XX mm Stylet)*	46569	Steril *Sterile*	EN ISO 5361 (2016)	Kural 5 Rule 5
54	555 0XXX 1 556 0XXX 1 055 XXXX 1 095 22XX 1	Trakeostomi Tüp *Tracheostomy Tube*	35404	Steril *Sterile*	EN 1282-2 (2005- A1:2009) EN ISO 5366 (2016)	Kural 5 Rule 5
55	560 200X 1 560 2001 1	Nasal Oksijen Kanülü *Nasal Oxygen Cannula*	35201	Steril *Sterile*	NA	Kural 2 Rule 2
56	563 XXXX 1 056 XXXX 1	Oksijen Kateteri *Oxygen Catheter*	35203	Steril *Sterile*	NA	Kural 2 Rule 2

57	565 XXXX 1 056 XXXX 1	Oksijen Bağlantı Hortumu *Oxygen Connecting Tube*	12875	Steril *Sterile*	EN 1617 (1997) ISO 20697 (2018)	Kural 2 Rule 2
58	573 0X7X 1 057 0X7X 1	Gaz Örnekleme Hattı *Gas Sampling Line*	45566	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
59	723 XX70 1 726 XX70 1 724 XXXX 1 072 XXXX 1	Cerrahi Örme Bant *Surgical Braided Tape*	36082	Steril *Sterile*	NA	Kural 7 Rule 7
60	760 XXXX 1 076 XXXX 1	Üç Yollu Musluk *Three Way Stopcock*	32172	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
61	765 XXXX 1 076 XXXX 1	Manifold *Manifold*	32172	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
62	790 XX01 1 079 XXXX 1	Redon Dren *Redon Drain*	11305	Steril *Sterile*	ISO 20697 (2018)	Kural 7 Rule 7
63	330 0450 1	Koroner Arter Retraksiyon Klipsi-3.0mm *Coronary Artery Retraction Clips-3.0mm*	47991	Steril *Sterile*	NA	Kural 6 Rule 6
64	330 0451 1	Koroner Arter Retraksiyon Klipsi-5.0mm Coronary Artery Retraction Clip-5.0mm	47991	Steril *Sterile*	NA	Kural 6 Rule 6

Sınıf Im Ürünler / *Class Im Products*

Sıra No	**Ürün Referansı**	**Ürün Adı**	**GMDN Kodu**	**Sterilite Durumu**	**İlgili Ürün Standardı**	**Ürün Risk Kuralı**
No	*Product Reference*	*Product Name*	GMDN Code	Sterility State	*Related Product Standard*	Device Risk Rule
1	186 XXXX 2	B-Spiro Nefes Egzersiz Cihazı *B-Spiro Volumetric Exerciser*	31266	Non-Steril Non-Sterile	NA	Kural 5 Rule 5

Sınıf Is Ürünler / *Class Is Products*

Sıra No *No*	**Ürün Referansı** *Product Reference*	**Ürün Adı** *Product Name*	**GMDN Kodu** GMDN Code	**Sterilite Durumu** Sterility State	**İlgili Ürün Standardı** *Related Product Standard*	**Ürün Risk Kuralı** Device Risk Rule
1	100 XXXX 1 101 XXXX 1 102 XXXX 1 103 XXXX 1 010 XXXX 1	I.V. İnfüzyon Seti *I. V. Infusion Set*	58977	Steril *Sterile*	ISO 8536-4 (2019) EN ISO 8536-8 (2015)	Kural 2 Rule 2

2	106 XXXX 1 107 000X 1	Damla Ayar Seti *Flow Regulator*	36244	Steril *Sterile*	ISO 80369-7 (2016) ISO 8536-4 (2019)	Kural 2 Rule 2
3	106 000X 1 107 000X 1 010 05XX 1	Infüzyon Seti-Damla Ayarlı *I.V. Infusion Set w/Flowmeter*	58977	Steril *Sterile*	ISO 8536-4 (2019) ISO 8536-8 (2015)	Kural 2 Rule 2
4	120 XXXX 1 121 XXXX 1 122 XXXX 1 012 XXXX 1	Uzatma Hatları Extention Lines	12170	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
5	125 0005 1 125 0001 1 012 XXXX 1	Stoper / İnstoper *Stopper/ Instopper*	31667	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
6	125 0007 1 012 XXXX 1	Kombi Stoper *Combi stopper*	31667	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
7	125 0010 1 012 XXXX 1	Transfer Set	41222	Steril *Sterile*	NA	Kural 1 Rule 1
8	125 10XX 1 130 XXXX 1 131 XXXX 1 012 XXXX 1	B Safe	42727	Steril *Sterile*	ISO 80369-1 (2018) ISO 80369-7 (2016) ISO 80369-20 (2015)	Kural 2 Rule 2
9	131 00XX 1 132 00XX 1 133 XXXX 1 124 XXXX 1 013 XXXX 1	B Safe Valfli Uzatma-İkili/Üçlü/T-Konnektörlü *Extension Line w/B-Safe Duo/Triple/T-Connector*	12170	Steril *Sterile*	ISO 80369-1 (2018) ISO 80369-7 (2016) ISO 80369-20 (2015)	Kural 2 Rule 2
10	135 XXXX 1 138 XXXX 1 013 80XX 1	Basınca Dayanıklı Uzatma Hatları *Pressure Extention Lines*	35529	Steril *Sterile*	ISO 80369-7 (2016) ISO 8536-9 (2015)	Kural 2 Rule 2
11	222 XXXX 1 223 XXXX 1 226 XXXX 1 022 XXXX 1	İdrar Torbası *Urine Collection Bag*	58921 58922	Steril *Sterile*	EN ISO 8669-2 (1996)	Kural 1 Rule 1
12	022 XXXX 1	Bacak İdrar Torbası *Leg Bag*	58924	Steril *Sterile*	NA	Kural 1 Rule 1
13	228 XXXX 1 022 XXXX 1	Lavman Seti Lavman Torba *Enema Set* *Enema Bag*	35050	Steril *Sterile*	NA	Kural 5 Rule 5
14	230 0001 1 023 0001 1	Göbek Kordon Klempi *Umbilical Cord Clamp*	43998	Steril *Sterile*	TS 6782: 1989 (T1:1994)	Kural 1 Rule 1
15	235 0001 1 023 0001 1	Konik Konnektör *Conical Connector*	44545	Steril *Sterile*	NA	Kural 1 Rule 1

16	236 XXXX 1 023 0001 1	Hortum Konnektörü *Tubing Connector*	44545	Steril *Sterile*	NA	Kural 2 Rule 2
17	236 1001 1	Mekonyum Aspiratör Konnektörü *Meconium Aspirator Connector*	35917	Steril *Sterile*	NA	Kural 2 Rule 2
18	238 0001 1 238 0011 1 023 XXXX 1	Kateter Tıkacı *Spigot*	31667	Steril *Sterile*	NA	Kural 1 Rule 1
19	240 0001 1 024 0001 1	Kapkon Konnektör *Kapkon Connector*	44545	Steril *Sterile*	NA	Kural 1 Rule 1
20	430 XXXX 1 043 XXX1 1	TUR Set	46102	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
21	450 XXX1 1 045 XXXX 1	Artroskopi Set *Arthroscopy Set*	46102	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2
22	550 0001 1 550 0002 1 550 0003 1 055 XXXX 1	Entübasyon Stilet *Entubation Stylet*	37469	Steril *Sterile*	NA	Kural 5 Rule 5
23	595 10XX 1	Vajinal Spekulum *Vaginal Specula*	37468	Steril *Sterile*	TS 5537:1988 T3: 2003	Kural 5 Rule 5
24	750 XXXX 1 075 XXXX 1	Düz Konnektör *Straight Connector*	35338	Steril *Sterile*	NA	Kural 2 Rule 2
25	751 XXXX 1 075 XXXX 1	Düz Luer Konnektör *Straight Luer Connector*	35338	Steril *Sterile*	NA	Kural 2 Rule 2
26	754 XXXX 1 075 XXXX 1	Y Konnektör *Y Connector*	35338	Steril *Sterile*	NA	Kural 2 Rule 2
27	755 XXXX 1 075 XXXX 1	Y Luer Konnektör *Y Luer Connector*	35338	Steril *Sterile*	NA	Kural 2 Rule 2
28	900 XXXX 1 095 90XX 1 090 XXXX 1	Guedel Havayolu *Guedel Airway*	42424	Steril *Sterile*	EN ISO 5364 (2016)	Kural 2 Rule 2
29	034 XXXX 1	Kontrol Şırıngası *Control Syringe*	15286	Steril *Sterile*	ISO 80369-7 (2016)	Kural 2 Rule 2

Sınıf Is-Im Ürünler / *Class Is & Im Products*

Sıra No *No*	**Ürün Referansı** *Product Reference*	**Ürün Adı** *Product Name*	**GMDN Kodu** GMDN Code	**Sterilite Durumu** Sterility State	**İlgili Ürün Standardı** *Related Product Standard*	**Ürün Risk Kuralı** Device Risk Rule
1	010 XXXX 1 105 XXXX 1 095 11XX 1	I.V. Infüzyon Seti-Büretli *I.V. Infusion Set-w/Burette*	12159	Steril *Sterile*	EN ISO 8536-5 (2013) ISO 80369-7 (2016)	Kural 2 Rule 2

2	011 XXXX 1 110 0001 1	C. V. P. SET *Central Venous Pressure Monitoring Set*	35529	Steril *Sterile*	ISO 8536-4 (2019) ISO 80369-7 (2016)	Kural 2 Rule 2
3	017 XXXX 1 175 XXXX 1	BPDS- Göğüs drenaj seti *Pleural Drainage Set*	10817	Steril *Sterile*	ISO 20697 (2018)	Kural 1 Rule 1
4	017 XXXX 1 176 200X 1	BTDS –Toraks drenaj seti *Thoracic Drainage Set*	10817	Steril *Sterile*	ISO 20697 (2018)	Kural 1 Rule 1
5	227 XXXX 1 022 XXXX 1	Ürimetre *Urimeter*	32072	Steril *Sterile*	EN ISO 8669-2 (1996)	Kural 1 Rule 1
6	022 7XXX 1 227 10XX 1	Urimetre İdrar Torbalı *Urimeter w/Urine Bag*	32072	Steril *Sterile*	EN ISO 8669-2 (1996)	Kural 1 Rule 1
7	027 1023 1	Ürimetre 500 Plus - İğnesiz Num. Portlu-Çek Valf *Urimeter 500 Plus-Needleless Sample-Check Valve*	32072	Steril *Sterile*	EN ISO 8669-2 (1996)	Kural 1 Rule 1
8	022 7404 1	Urimeter 500 Plus Safety	32072	Steril Sterile	EN ISO 8669-2 (1996)	Kural 1 Rule 1

Açıklama: XXXX ürünün farklı uzunluk, ölçü gibi farklılıklarını ifade etmektedir.
Explanation:XXXX means different length, sizes etc. product.
NA: İlgili ürün standardı bulunmamaktadır./ **There is no related product standard.**

ONAY / APPROVAL	
Yayın Yeri ve İmza Tarihi **Signature Date and Place of Issue**	**TURKEY/ 07.10.2022**
Yetkili kişinin adı, ünvanı, imzası ve firma kaşesi **Name, title, signature of authorized person with company cachet**	
Kalite Güvence Uzmanı **Quality Assurance Specialist**	Kalite ve Regülasyon Yöneticisi **Quailty and Regulatory Exercutive**
Selda ÇAKMAK	Aysel YILDIRIM
Selda ÇAKMAK Kalite Güvence Uzmanı *Quality Assurance Specialist*	Aysel YILDIRIM Kalite ve Regülasyon Yöneticisi *Quality and Regulatory Executive*