EC DECLARATION OF CONFORMITY

Doc. No.: IDN – 200103AB

Manufacturer:
Name: Anji SPENQ Industrial Co., Ltd.
Address: F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China
Tel: 0086-572-5882801 Fax: 0086-572-5676519

EC-Representative:
Name: SUNGO Europe B. V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, The Netherlands

Manufacturing Sites:
F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China

Product Names: First Aid Bandage, High Elastic Bandage, Elastic Adhesive Bandage, Cotton Crepe Bandage, Ideal Bandage, Gauze Bandage, Plaster of Paris Bandage, Medical Bandage, Orthopaedic Casting Tape, Orthopaedic Padding, Cohesive Bandage, Tubular Net Bandage, Stockinet Bandage, Triangular Bandage, Zinc Oxide Tape, Silk Tape, Non-woven Tape, PE Tape, Medical Tape, Non- woven Wound Dressing Tape, PU Wound Dressing Tape, Waterproof Adhesive Tape, Absorbent Underpad, Absorbent Cotton Wool, Cotton Ball, Dental Cotton Ball, Cotton Bud, Gauze Roll, Gauze Swab, Colostomy Bag, Urostomy Bag, Non-woven Swab, Nurse Cap, Doctor Cap, Mob Cap, Hospital Bed Sheet, Medical Face Mask, Anaesthesia Mask, Uzi Gel, Shoe Cover, Dental Bib, Urine Container, Stool Container, Pipettes, Pipette Tips, Slide for Blood Test, Test Tubes, Adult Diaper, Isolation Gown, Dental Set, Sterilization Strip, Smoothbore Corrugated Breathing Circuit, Petri Dish, PE Gloves, Heat and Moisture Exchange Filter, Holder for Blood Collection Needle, Extension Tube, Blood Lancet Device, Plastic Forcep, ECG Electrode, Coverall, Face Shield, Urine Bag for Men.

Classification of products: I NON-STERILE according to Annex IX of the Directive 93/42/EEC.
The products bear the mark

CE

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC (Self-Certification).
The above-mentioned declaration of conformity is exclusive under the responsibility of

Anji SPENQ Industrial Co. Ltd.

Declaration person: Li Wenhu
Position: General Manager
Place: Anji City, China
Signature of issue person:
Date: January 23, 2020

安吉鑫洋进出口有限公司
ANJI SPENQ INDUSTRIAL CO., LTD.

Digitally signed by Chitic Vlad
Date: 2024.04.22 20:58:08 EEST
Reason: MoldSign Signature
Location: Moldova

SPENQ MEDICAL

EC DECLARATION OF CONFORMITY

Doc. No.: IDN – 220801AE

Manufacturer:
Name: Anji SPENQ Industrial Co., Ltd.
Address: F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China
Tel: 0086-572-5882801 Fax: 0086-572-5676519

EC-Representative:
Name: SUNGO Europe B. V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, The Netherlands

Manufacturing Sites:
F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China

Product Names: Capsicum Plaster

Classification of products: I NON-STERILE according to Annex IX of the Directive 93/42/EEC.
The products bear the mark

CE

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

COPIA CORESPUNDE ORIGINALULUI

TÜV SÜD Product Service GmbH (ID: 0123)
Ridlerstraße 65, 80339 München, Germany
Certificate No.: Q6 080946 0012 Rev. 01
Issue date: 24.11.2019
Expiry date: 23.11.2022

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC (Self-Certification).
The above-mentioned declaration of conformity is exclusive under the responsibility of

Anji SPENQ Industrial Co. Ltd.

Declaration person: Li Wenhu
Position: General Manager
Place: Anji City, China
Signature of issue person:
Date: August 01, 2022

安吉鑫洋进出口有限公司
ANJI SPENQ INDUSTRIAL CO., LTD

Declaration of Conformity

Manufacturer:
Name: Anji SPENQ Industrial Co., Ltd.
Address: F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China
Tel: 0086-572-5882801 Fax: 0086-572-5676519

EC-Representative:
Name: SUNGO Europe B. V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, The Netherlands

Manufacturing Sites:
F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China

Product Names: Disposable Vaginal Speculums, Disposable Colostomy Bags, Disposable Vaginal Irrigation Sets, Urine Bags, Umbilical Cord Clamps, Sterile Latex Examination Gloves, Wound Plasters, Liquid Transfusion Plasters, Adhesive Wound Dressings, First-Aid Kits, Sterile Gauze Sponges, Rectal Tubes, Skin Closure Strips, Surgical Drapes, Sterile Surgical Gown, Absorbent Cotton Rolls, Absorbent Cotton Balls, Absorbent Cotton Pads, Eye Pad, Abdominal Pads, Non-woven Swabs, Lab Sponges, Gauze Roll

Classification of products: I STERILE
CE Conformity Assessment Route: MDD 93/42/EEC Annex V.3

We hereby declare:
The above-mentioned CE-marked products comply with medical device directives and standards, and meet the intended use; all supporting documents are proved by manufacturer and notified body, and the authenticity is committed.

Directive

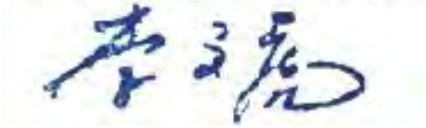
Applicable directives: Medical Device Directives – MDD 93/42/EEC (14.06.1993).
Standards: All applicable EU-harmonized standards.
Certification body: TUV SUD Product Service GmbH certifies the quality management system of our company.

Identification number: CE0123
EC Certification No.: G2S 080946 0010 Rev. 03
Expiry date of CE Certificate: 2024-05-26

The distribution of first CE-marked products:
Location: F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China

Declaration person: Li Wenhu
Position: General Manager
Place: Anji City, China
Signature of issue person:
Date: February 25, 2021

安吉鑫洋进出口有限公司
ANJI SPENQ INDUSTRIAL CO .LTD



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CE

EU DECLARATION OF CONFORMITY

Company name : HİRA PAMUK PLASTİK KOZMETİK TEMİZLİK SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Adress : Erkenez Mh. Mustafa Yilmaz Cd. No: 3/A Dulkadiroglu KAHRAMANMARAŞ TÜRKİYE

We declare that we are the manufacturer of the devices listed below and that the devices comply with the Medical Device Regulation (EU) 2017/745 (MDR) and meet all relevant requirements within the MDR.

Conformity Assessment Route: Annex-IV Declaration of Conformity (Annex II & Annex III)

The products are in Class I according to rule 1, 5 in Annex VIII of the Medical Device Regulation.

Basic UDI-DI : 8682139495HZP07HQ

COPIA CORESPUNDE ORIGINALULUI

This Declaration of Conformity has been created under the sole responsibility of the manufacturer.

Product Name and Types

Brand name	Name of the product
Bambino Cotton	Hydrophilic Roll Cotton 100 gr
Bambino Cotton	Hydrophilic Zigzag Cotton 100 gr
Bambino Cotton	Hydrophilic Zigzag Cotton 200 gr
Bambino Cotton	Hydrophilic Zigzag Cotton 250 gr
Bambino Cotton	Hydrophilic Zigzag Cotton 500 gr
Bambino Cotton	Hydrophilic Roll Cotton 500 gr
Bambino Cotton	Hydrophilic Roll Cotton 1000 gr
Bambino Cotton	Hydrophilic Zigzag Cotton 50 gr
Bambino Cotton	Hydrophilic Zigzag Cotton 100 gr
Bambino Cotton	Hydrophilic Zigzag Cotton 200 gr
Bambino Cotton	Hydrophilic Zigzag Cotton 250 gr
Bambino Cotton	Hydrophilic Zigzag Cotton 500 gr
Bambino Cotton	Hydrophilic Roll Cotton 100
Bambino Cotton	Hydrophilic Roll Cotton 500
Bambino Cotton	Hydrophilic Roll Cotton 1000
Bambino Cotton	Hydrophilic Zigzag Cotton 50 gr

HİRA PAMUK PLAS. KOZM. TEM. SAN. VE TİC. LTD. Ş.
Aksu VD. 463 863 7735
Erkenez Mh. Mustafa Yılmaz Cd. No:
Dulkadiroglu / KAHRAMANMARAŞ

Bambino Cotton	Hydrophilic Cotton 1000 gr Zigzag
Bambino Cotton	Hydrophilic Cotton 200 gr Zigzag
Bambino Cotton	Hydrophilic Roll Cotton 500 gr
Bambino Cotton	Hydrophilic Roll Cotton 50 gr Zigzag
Bambino Cotton	Hydrophilic Roll Cotton 1000 gr

COPIA CORESPUNDE CU ORIGINALUL

Issue Date: **12.08 .2021**

Signature /
General Manager /PAKİZE ÖNGEL

HİRA PAMUK PLAS. KOZM. TEM. SAN. VE TİC. LTD. ŞTİ.
Aksu V.D. 463 063 7735
Erkenez Mah. Ümmet Yılmaz Cd. No. 3/A
Dulkadiroğlu / KAHRAMANMARAŞ

Declaration of Conformity

Manufacturer:
Name: Shaoxing Gangfeng Hospital Products Co., Ltd.
Address: Gaobu Industrial Zone, Gaobu, 312035 Shaoxing, People's Republic of China
Tel: 0086-575-88086566 Fax: 0086-575-88081711

EC-Representative:
Name: SUNGO Europe B. V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, The Netherlands

Manufacturing Sites:
Gaobu Industrial Zone, Gaobu, 312035 Shaoxing, People's Republic of China

Product Names: Gauze Swabs (Sponges), Gauze Balls, Sterile Gauze Bandages and Sterile Non-woven Would Care Products, Gauze in Roll, Gauze in Zigzag, Cutted Gauze, Medical Elastic Bandage, First Aid Kits, Absorbent Cotton, Cotton Tip Applicator

Classification of products: I STERILE
CE Conformity Assessment Route: MDD 93/42/EEC Annex V.3

We hereby declare:
The above-mentioned CE-marked products comply with medical device directives and standards, and meet the intended use; all supporting documents are proved by manufacturer and notified body, and the authenticity is committed.

Directive

Applicable directives: Medical Device Directives – MDD 93/42/EEC (14.06.1993).
Standards: All applicable EU-harmonized standards.
Certification body: TUV SUD Product Service GmbH certifies the quality management system of our company.

Identification number: CE0123
EC Certification No.: G2S 038500 0026 Rev. 00
Expiry date of CE Certificate: 2024-05-26

The distribution of first CE-marked products:
Location: Gaobu Industrial Zone, Gaobu, 312035 Shaoxing, People's Republic of China

Declaration person: Michelle Tao
Position: Director
Place: Gaobu City, China
Signature of issue person:
Date: November 11, 2019

绍兴滨峰医用品有限公司
Shaoxing Gangfeng Hospital Products Co.,Ltd.
王纪荣

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 038500 0026 Rev. 00

Manufacturer

Shaoxing Gangfeng Hospital Products Co., Ltd.
Gaobu Industrial Zone, Gaobu
312035 Shaoxing
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Gauze Swabs (Sponges), Gauze Balls, Gauze Bandages and Non-woven Wound Care Products (Class I Sterile), Absorbent Gauze (Gauze in Roll, Gauze in Zigzag, Cutted Gauze), Medical Elastic Bandage, First Aid Kits, Absorbent Cotton, Cotton Tip Applicators

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH19026EXT01

Valid from: 2019-10-28
Valid until: 2024-05-26

Date, 2019-10-28

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

A4 / 07.17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 038500 0026 Rev. 00

Facility(ies):

Shaoxing Gangfeng Hospital Products Co., Ltd.
Gaobu Industrial Zone, Gaobu, 312035 Shaoxing, PEOPLE'S REPUBLIC OF CHINA

.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

UkrPharmExport LLC

Address:Sobornosti ave. 30-A, office 309-312, 02154, Kyiv, Ukraine;
Tel./Fax: (044) 502-54-87; (044) 451-44-80;
Web: www.ufe.com.ua; E-mail: arm@ufe.com.ua

EC Declaration of Conformity

We, UkrPharmExport LLC, with address of Sobornosti ave. 30-A, office 309-312, 02154, Kyiv, Ukraine as manufacturer hereby declare under our sole responsibility that the products listed in Annex to this Declaration comply with the provisions of the Council Directive 93/42/EC.

The Manufacturer has designed the following authorized representative within the European Market:

Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net

The devices are Class I following Rule 1 and 4 of Annex IX of the Council Directive 93/42/EC.

The following conformity procedure has been applied in order to affix the CE marking on the devices:

Class 1: *the procedure referred to in Annex VII*

This Declaration is valid for all products bearing the CE marking placed on the European market as of the date of signature of this Declaration.

Kyiv, Ukraine ***02/02/2021***

Bohdan Khrushch.
Director of UkrPharmExport LLC

UkrPharmExport LLC

Address:Sobornosti ave. 30-A, office 309-312, 02154, Kyiv, Ukraine;
Tel./Fax: (044) 502-54-87; (044) 451-44-80;
Web: www.ufe.com.ua; E-mail: arm@ufe.com.ua

ANNEX TO EC DECLARATION OF CONFORMITY

List of Devices Covered by the Declaration of Conformity

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN Code	Class	Rule
1.	NA	Rivulet Cotton Wool - Surgical absorbent medical cotton wool in roll	Cotton wool roll, non-sterile	For medical manipulation and hygienic care. Intended for use as ready-made dressings. Scope - treatment and prevention facilities and individual use.	58232	I	4
2.	NA	Rivulet Cotton Wool - Hygienic absorbent medical cotton wool in roll	Cotton wool roll, non-sterile		58232	I	4
3.	NA	Rivulet Cotton Wool - Surgical absorbent medical cotton wool in zigzag tape	Cotton pleats		58234	I	4
4.	NA	Rivulet Cotton Wool - Hygienic absorbent medical cotton wool in zigzag tape	Cotton pleats		58234	I	4
5.	NA	Rivulet Cotton Wool - Surgical absorbent medical cotton wool in perforated tape	Cotton wool roll, non-sterile		58232	I	4
6.	NA	Rivulet Cotton Wool - Hygienic absorbent medical cotton wool in perforated tape	Cotton wool roll, non-sterile		58232	I	4

UkrPharmExport LLC

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Web: www.ufe.com.ua; E-mail: arm@ufe.com.ua

7.	NA	Rivulet gauze bandage - Medical gauze bandage	Woven gauze roll, non-sterile	Intending: ready-made dressings and for the production of surgical dressings. Used as a fixing agent. Structure provides high hygroscopicity. Scope - treatment and prevention facilities and individual use.	48126	I	1
8.	NA	Rivulet - Medical elastic bandage for fixation in tape	Pressure bandage, non-latex, non-sterile, reusable	The fixing bandage is used for fixing compresses, medical bandages, dressings of all types, cannulas, etc.	61223	I	1
9.	NA	Rivulet - Medical elastic bandage in tape short stretch	Pressure bandage, non-latex, non-sterile, reusable	Prevention, improvement and treatment of varicose veins, chronic thrombophlebitis, support of joints and soft tissues at rest after injuries and operations.	61223	I	1
10.	NA	Rivulet - Medical elastic bandage in tape medium stretch	Pressure bandage, non-latex, non-sterile, reusable		61223	I	1
11.	NA	Rivulet - Medical elastic bandage in tape high stretch	Pressure bandage, non-latex, non-sterile, reusable		61223	I	1
12.	NA	Rivulet - Medical elastic adhesive bandage in tape short stretch	Pressure bandage, non-latex, non-sterile, reusable	Intended for use during rehabilitation; sports medicine; neurology; pediatrics; military medical rehabilitation.	61223	I	1
13.	NA	Rivulet - Bandage for fixation of the wrist joint	Wrist binder, reusable	Intended for use as rehabilitation period after plaster bandage wearing or in case of ligamentous injury along with fixation of radiocarpal joint and thumb joint, in case of arthrosis, arthritis etc.	43817	I	1
14.	NA	Rivulet - Supporting arm bandage	Pressure-management bandage, padded	Bandage is used in fractures of hand, sprain and in the postoperative period.	58963	I	1

UkrPharmExport LLC

Address:Sobornosti ave. 30-A, office 309-312, 02154, Kyiv, Ukraine;
Tel./Fax: (044) 502-54-87; (044) 451-44-80;
Web: www.ufe.com.ua; E-mail: arm@ufe.com.ua

15.	NA	Rivulet - Bandage medical prophylactic surgical elastic with edges of rigidity	Pressure bandage, non-latex, non-sterile, reusable	Bandage is used for osteochondrosis, radiculitis, landslides and hernias of intervertebral discs jamming nerve injures, chronic pain in the lumbosacral spine.	61223	I	1
16.	NA	Rivulet - Bandage postoperative	Pressure bandage, non-latex, non-sterile, reusable	Bandage is shown at early immobilization after surgery for organs of abdominal cavity including caesarean section; prevention of formation of postoperative hernia the anterior abdominal wall (muscle weakness, after large cuts); strangulation prevention of postoperative hernia that can be set, linea alba hernias, umbilical hernias.	61223	I	1
17.	NA	Rivulet - Knee joint Bandage	Knee support/thermal therapy bandage	The knee joint bandage is applied in the following pathologies: arthritis, arthrosis, deforming arthritis, minor injuries and bruises, minor damage and sprains, synovitis, bursitis, as well as for the prevention of injuries and illnesses with physical exertion. It is used in the rehabilitation period, after wearing a plaster cast.	56282	I	1
18.	NA	Rivulet - Knee joint Warming Bandage	Knee support/thermal therapy bandage	A bandage is ensuring of the soft fixing and compression of knee-joint at traumas and damages of copulas, at the pains in a joint caused by arthritis, bursitis and synovitis.	56282	I	1
19.	NA	Rivulet - Elastic bandage in the shape of eight for fixation of the ankle joint	Ankle binder, reusable	The bandage is used is ligamentous injury of an ankle joint and foot; rehabilitation period after plaster bandage wearing; prevention of dislocation or injuries during sporting activities; prevention of sprains of an ankle joint in persons who work hard; decrease of the loading on an ankle joint and Achilles' tendon.	44481	I	1
20.	NA	Rivulet - Bandage pre / postnatal partum	Abdominal binder, reusable	The bandage is used to remove tension in the lumbar-sacral spine, reduces pain. Protects the abdominal wall tissue against excessive stretching.	47217	I	1

UkrPharmExport LLC

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Tel./Fax: (044) 502-54-87; (044) 451-44-80;
Web: www.ufe.com.ua; E-mail: arm@ufe.com.ua

21.	NA	Rivulet - Bandage Lumbar-sacral	Tubular support bandage, non-latex, reusable	The bandage is used to easy fixing and stabilizing the lumbar spine as well as back muscles relax and anti-pain effect. The bandage is used for pain in the lumbar spine of various etiologies, osteochondrosis, spondylolisthesis, lumbosacral spine spondylolisthesis including pain syndrome. Sciatica, myositis, bruising of the lumbar-sacral spine. Recovering from injures and operations on the lumbar-sacral spine.	61652	I	1
22.	NA	Rivulet - Warming elastic belt	Tubular support bandage, non-latex, reusable	The warming elastic belt is used in the treatment and prevention of neuritis, radiculitis, myositis. The product reduces the pain syndrome, removes muscle tension, and also speeds up the healing process. Due to the soft support, the use of the belt has a beneficial effect on the internal organs and improves the blood circulation.	61652	I	1
23.	NA	Rivulet - Posture corrector (reclinator) elastic with stiffening ribs	Wearable lumbar spine traction device	The bandage is used to the period of rehabilitation after injuries and operations on the thoracic spine; damage of posture in children and adults; spondylopathy and osteochondropathy of the thoracic spine; increased physical activity, forced long stay in a static position; middle and late periods of rehabilitation after injuries and operations on the lumbar spine.	61214	I	1
24.	NA	Rivulet - Posture corrector (reclinator) elastic clavicular for children	Wearable lumbar spine traction device	The clavicular posture corrector is used for treatment and rehabilitation after injuries and operations on the upper thoracic spine, clavicle. Applied with kyphosis, kyphoscoliosis, pterygoid scapula and juvenile osteochondropathly, used in osteochondrosis of the upper thoracic spine, mild spondylopathy, osteoporosis.	61214	I	1
25.	NA	Rivulet - Posture corrector (reclinator) elastic for	Wearable lumbar spine traction device	The clavicular posture corrector is used for treatment and rehabilitation after injuries and operations on the upper thoracic	61214	I	1

UkrPharmExport LLC

Address:Sobornosti ave. 30-A, office 309-312, 02154, Kyiv, Ukraine;
Tel./Fax: (044) 502-54-87; (044) 451-44-80;
Web: www.ufe.com.ua; E-mail: arm@ufe.com.ua

		collarbone		spine, clavicle. Applied with kyphosis, kyphoscoliosis, pterygoid scapula and juvenile osteochondropathly, used in osteochondrosis of the upper thoracic spine, mild spondylopathy, osteoporosis.			

EC Declaration of Conformity

MANUFACTURER	:	**Tules Medikal SAN. ve TİC. A.Ş.**
ADDRESS	:	Fatih Mahallesi 1213 Sok. No.8/A Gaziemir/İZMİR
PHONE	:	+90232 332 11 51
FAX	:	+90232 332 11 51
E-MAIL	:	info@tulesmedikal.com.tr
BRAND LABEL	:	TULES
PRODUCT GROUP	:	Sterile Non-woven Compress
CLASSIFICATION	:	Class IIA
ASSESSTMENT ROUTE	:	Medical Device Directive (93/42/EEC) ANNEX V
CLASSIFICATION RULE	:	Medical Device Directive (93/42/EEC) ANNEX IX – Rule 6
GMDN	:	48131 (Non-woven gauze pad, sterile) 39404 (Radiopaque non-woven surgical sponge, sterile)

We hereby declare that above mentioned products meet the provisions of the latest version of European Medical Device Directive 93/42/EEC. All supporting documentation is retained under the premises of the manufacturer.

We declare that the products do not incorporate a substance of a human blood derivative, animal originated tissues, phthalates, medicinal product, latex, radioactive material and electromagnetic waves.

STANDARDS	:	TS EN ISO 13485	TS EN ISO 15223-1	TS EN ISO 10993-1
		TS EN ISO 14971	TS EN 1041+A1	TS EN ISO 10993-5
		MDD 93/42/EEC	TS EN 1644-1	TS EN ISO 10993-7
		MEDDEV 2.7/1 rev. 4	TS EN 1644-2	TS EN ISO 10993-10
		MEDDEV 2.12-1 rev. 8		

CE CERTIFICATE NO	:	1817C05210502
CE CERTIFICATION DATE	:	25/05/2021
CE CERT. VALID UNTIL	:	26/05/2024
NOTIFIED BODY / NO	:	G.F.I. Health Technology Certification Ltd. (Cyprus) / 2803
PLACE OF ISSUE	:	İzmir / TÜRKİYE
DATE OF ISSUE	:	25/05/2021
AUTHORIZED PERSON	:	Hasan KUYUCU
TITLE	:	General Manager
SIGNATURE	:	

COPIA CORESPUNDE CU ORIGINALUL

TULES MEDİKAL SANAYİ VE TİCARET A.Ş.

HTCert

Health Technology Certification

EC-CERTIFICATE

PRODUCTION QUALITY ASSURANCE

This is to certify that the
quality management system of

TULES MEDIKAL SANAYI VE TICARET ANONIM SIRKETI

FATIH MAHALLESI 1213 SOKAK NO:8/A GAZIEMIR
35410, IZMIR, TURKEY

COPIA CORESPUNDE ORIGINALULUI

for manufacturing and final testing of

Sterile and non-sterile wound care devices.

Further details are given overleaf

Certificate No:	**1817C05210502**
Issue Date:	**25/05/2021**
Original Approval:	**25/05/2021**
Valid until:	**26/05/2024**
References:	**W001 1817 01**

HTCert is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification number **2803**

fulfills the requirements of Annex V of Council Directive 93/42/EEC.

The use of CE Marking followed by the HTCert Notified Body identification number 2803 for the devices listed on the certificate is hereby authorised. The certificate remains valid subject to satisfactory surveillance audits, periodic or unexpected. Any significant changes in design or manufacture may render this certificate invalid. For class I sterile devices the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director

JACOVIDES TOWER, 81-83 GRIVAS DIGHENIS AV. CY-1090, NICOSIA, CYPRUS. T: +357 220 60 771, F: +357 220 60 772
info@htcert.com, www.htcert.com

HTCert

Health Technology Certification

Attachment to Certificate

No: 1817C05210502 Issued: 25/05/2021

Class I sterile devices:

- Sterile Holders for Limbs, Endotracheal Tubes and Tracheostomy Tubes
- Sterile Phototherapy Eye Protector

Under the brand name "TULES"

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IIa devices:

- Sterile and non-sterile Compresses / Gauzes (including sponges, pads & swabs) with and without X-ray:
  - Woven Compresses / Gauzes with and without cotton
  - Woven Abdominal Compresses / Gauzes, with and without cotton
  - Non-woven Compresses / Gauzes, with and without cotton
  - Non-woven Abdominal Compresses / Gauzes, with and without cotton
  - Woven Abdominal Compresses / Gauzes, filled with non-woven

Under the following brand names:

TULES, ROLL, MAXWELL, MEDIKAL REYONUM, MEDBAN, TUEM MEDIKAL, CANSIN PLAST.

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director

JACOVIDES TOWER, 81-83 GRIVAS DIGHENIS AV. CY-1090, NICOSIA, CYPRUS. T: +357 220 60 771. F: +357 220 60 772
info@htcert.com, www.htcert.com

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 088678 0004 Rev. 02

Manufacturer	**Taizhou Kangping Medical Science And Technology Co., Ltd.** Building 3 No.27, Tai'an Road Hailing Industrial Park 225300 Taizhou, Jiangsu PEOPLE'S REPUBLIC OF CHINA
EC-Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse 8, 80807 München, GERMANY
Product Category(ies):	**Sterile Pads (Alcohol Swabs), Eye Wash (Sodium chloride irrigation solution)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH18900EXT01

Valid from: 2019-07-12
Valid until: 2024-05-26

Date, 2019-07-12

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 088678 0004 Rev. 02

Facility(ies):

Taizhou Kangping Medical Science And Technology Co., Ltd.
Building 3 No.27, Tai'an Road, Hailing Industrial Park, 225300 Taizhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body •-Ridlerstraße 65 • 80339 Munich • Germany

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Declaration of Conformity

Manufacturer:
Name: Taizhou Kangping Medical Science And Technology Co., Ltd.
Address: Building 3 No.27, Tai'an Road Hailing Industrial Park 225300 Taizhou, Jiangsu, People's Republic Of China
Tel: 0086-523-86299168 Fax: 0086-523-86277168

EC-Representative:
Name: MedPath GmbH
Address: Mies-van-der-Rohe-Strasse 8, 80807 Munchen, Germany

Manufacturing Sites:
Building 3 No.27, Tai'an Road Hailing Industrial Park 225300 Taizhou, Jiangsu, People's Republic Of China

Product Name: Alcohol Prep Pad

Model: (LA-015)

Classification of products: I STERILE
CE Conformity Assessment Route: MDD 93/42/EEC Annex V.3

We hereby declare:
The above-mentioned CE-marked products comply with medical device directives and standards, and meet the intended use; all supporting documents are proved by manufacturer and notified body, and the authenticity is committed.

Directive

Applicable directives: Medical Device Directives – MDD 93/42/EEC (14.06.1993).
Standards: All applicable EU-harmonized standards.
Certification body: TUV SUD Product Service GmbH certifies the quality management system of our company.

Identification number: CE0123
EC Certification No.: G2S 088678 0004 Rev. 02
Expiry date of CE Certificate: 2024-05-26

The distribution of first CE-marked products:
Location: Building 3 No.27, Tai'an Road Hailing Industrial Park 225300 Taizhou, Jiangsu, People's Republic Of China

Declaration person: Mr. Evan Gao 陈阿平
Position: General Manager
Place: Taizhou, China
Signature of issue person:
Date: December 16, 2021 泰州市康平医疗科技有限公司

Taizhou KangPing Medical Science And Techology Co.,Ltd

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 080946 0007 Rev. 03

Manufacturer:

Anji SPENQ Industrial Co., Ltd.
F16, Building C
Anji Chamber of Commerce Mansion
No. 99 Tianhuangping South Road
313300 Anji County, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Anji SPENQ Industrial Co., Ltd.
F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Latex Foley Catheters, Oxygen Masks, Sterile Blood Lancets, Sterile Latex Surgical Gloves, Sterile Syringes for Single Use, Sterile Infusion Sets for Single Use, Sterile Intravenous Needles for Single Use, Sterile Hypodermic Needles for Single Use, Sterile Blood Transfusion Sets for Single Use, Nasal Oxygen Cannulaes, Suction Catheters, Stomach Tubes, Feeding Tubes, Nelaton Catheter, Disposable Surgical Blades, Endotracheal Tubes, Laryngeal Mask, Reinforced Endotracheal Tube, Mucus Extractor, Tracheostomy Tube, Silicone Foley Catheter

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH19601EXT01

Valid from: 2020-01-29

Valid until: 2024-05-26

Date, 2020-01-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DECLARATION OF CONFORMITY

Doc. No.: IDN – 210421AA

Manufacturer:
Name: Anji SPENQ Industrial Co., Ltd.
Address: F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China
Tel: 0086-572-5882801 Fax: 0086-572-5676519

EC-Representative:
Name: SUNGO Europe B. V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, The Netherlands

Manufacturing Sites:
F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China

Product Names: Latex Foley Catheters, Oxygen Masks, Sterile Blood Lancets, Sterile Latex Surgical Gloves, Sterile Syringes for Single Use, Sterile infusion Sets for Single Use, Sterile intravenous Needles for Single Use, Sterile Hypodermic Needles for Single Use, Sterile Blood Transfusion Sets for Single Use, Nasal Oxygen Cannulas, Suction Catheters, Stomach Tubes, Feeding Tubes, Nelaton Catheter, Disposable Surgical Blades, Endotracheal Tubes, Laryngeal Mask, Reinforced Endotracheal Tube, Mucus Extractor, Tracheostomy Tube, Silicone Foley Catheter.

Classification of products: IIa, IIb or III
CE Conformity Assessment Route: MDD 93/42/EEC Annex V.3

We hereby declare:
The above-mentioned CE-marked products comply with medical device directives and standards, and meet the intended use; all supporting documents are proved by manufacturer and notified body, and the authenticity is committed.

Directive

Applicable directives: Medical Device Directives – MDD 93/42/EEC (14.06.1993).
Standards: All applicable EU-harmonized standards.
Certification body: TUV SUD Product Service GmbH certifies the quality management system of our company.

Identification number: CE0123
EC Certification No.: G2S 080946 0007 Rev. 03
Expiry date of CE Certificate: 2024-05-26

The distribution of first CE-marked products:
Location: F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China

安吉鑫泽进出口有限公司
ANJI SPENQ INDUSTRIAL CO., LTD

Declaration person: Li Wenhu
Position: General Manager
Place: Anji City, China
Date: April 21, 2021

EC DECLARATION OF CONFORMITY

Doc. No.: IDN – 220801AA

Manufacturer:
Name: Anji SPENQ Industrial Co., Ltd.
Address: F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China
Tel: 0086-572-5882801 Fax: 0086-572-5676519

EC-Representative:
Name: SUNGO Europe B. V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, The Netherlands

Manufacturing Sites:
F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China

Product Names: Medical Tourniquet

Classification of products: I NON-STERILE according to Annex IX of the Directive 93/42/EEC.
The products bear the mark

CE

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Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV SÜD Product Service GmbH (ID: 0123)
Ridlerstraße 65, 80339 München, Germany
Certificate No.: Q6 080946 0012 Rev. 01
Issue date: 24.11.2019
Expiry date: 23.11.2022

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC (Self-Certification).
The above-mentioned declaration of conformity is exclusive under the responsibility of

Anji SPENQ Industrial Co. Ltd.

Declaration person: Li Wenhu
Position: General Manager
Place: Anji City, China
Signature of issue person:
Date: August 01, 2022

安吉鑫洋进出口有限公司
ANJI SPENQ INDUSTRIAL CO., LTD

TMS MEDİKAL PLASTİK ÜRÜNLER SAN. VE DIŞ TİC. LTD. ŞTİ.
İstanbul Deri OSB Mah. Alsancak Sk. No:3/A Tuzla - İSTANBUL
Tel: 0216 504 18 67 E-mail: info@tmsmedikal.com
Tuzla V.D.: 8450330385 - Tic. Sicil No: 972249-0
Mersis No: 0845033038500010
www.tmsmedikal.com

EU DECLERATION OF CONFIRMITY

According to Regulation (EU) 2017/745

1. **Manufacturer information:**
   1.1 Name: TMS MEDIKAL PLAST. URUN. SAN. VE DIS TIC. LTD. STI.
   1.2 Address: Istanbul Deri Osb. Mah. Alsancak Sok. No: 3/A Tuzla / Istanbul
2. **The undersigned states that this EU decleration of confirmity is issued under responsibility of TMS MEDIKAL.**
3. **Basic UDI-DI: 869886383T201791QT**
4. **Product information:**
   4.1 Product trade name and product code:

REF CODE & MODEL
T20179 Enema Set
T20174 Baby Urine Colector 100ml
T20175 Baby Urine Colector 100ml
T20176 Chamber Tri-Flo

5. **Product risk class according to annex VII, rule 1: class I**
6. **TMS MEDIKAL is registered in EUDAMED with actor code TR-MF-000019237**
7. **The undersigned declares that the products referred to in this statement are covered by the present declaration and they are in confirmity with Regulation (EU) 2017/745.**

Place: Tuzla / Istanbul TURKEY
Date 30.05.2022
Name: Tarık Alp Sarı
Function: General Manager

TMS MEDİKAL PLASTİK ÜRÜNLER SAN. DIŞ TİC. LTD. ŞTİ.
İstanbul Deri Organize Sanayi Bölgesi 35 6 No.lu Parsel Alsancak Sok. No 3/A Kat 1 Tuzla İstanbul/TURKEY
Tuzla V.D. 845 033 0385

REPUBLICA MOLDOVA CAMERA PENTRU CONTRACTE «NATUSANA» 1006800025657 SOCIETATEA CU RASPUNDERE LIMITATA

AT UYGUNLUK BEYANI
EC DECLARATION OF CONFORMITY

İMALATÇI/*MANUFACTURER* : **TMS MEDİKAL PLASTİK URUNLER SAN VE DIŞ TİC. LTD. STİ**

ADRES/*ADRESS* : **İstanbul Deri Osb Mah. Alsancak Sok No:3/A**
Tuzla /istanbul/TÜRKİYE

TEL/*PHONE* : +90 216 504 18 67

E-Mail : **info@tmsmedikal.com**

SINIFLANDIRMA
CLASSIFICATION : **MDD 93/42/EEC Tıbbi Cihaz Direktifi- EK IX, Kural 5, SINIF I**
Medical Device Directive-ANNEX IX, RULE 5, CLASS I

UYGUNLUK DEĞERLENDİRME : **MDD 93/42/EEC Tıbbi Cihaz Direktifi-**
EK V-Üretim Kalite Güvencesi
CONFORMITY ASSESMENT : ***MDD 93/42/EEC Medical Device Directive***
Annex V-Production Quality Assurance System

ÜRÜN ADI / *PRODUCT NAME* : ***VAGINAL SPECULUM***

ÜRÜN ADI/*PRODUCT NAME*	Tip	Model, Ref No	GMDN KODU/*GMDN CODE*	GMDN ADI/*GMDN NAME*
VAGINAL SPECULUM	LARGE	T201793	37468	*Vaginal speculum, single-use*
	MEDIUM	T201792		
	SMALL	T201791		

LİSTELİ ÜRÜNLERİN, TALİMATLAR KURULU TIBBİ CİHAZLAR KARARNAMESİ 93/42/ AT İÇİN GEREKLİ ŞARTLARA UYGUN OLDUĞUNU BEYAN EDERİZ. DESTEKLEYİCİ TÜM BELGELER ÜRETİCİNİN TESİSLERİNDE BULUNMAKTADIR.

WE HEREWITH DECLARE THAT THE ATTACHED PRODUCT LIST MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

İLGİLİ STANDARTLAR / *STANDARTS APPLIED* :

EN ISO 13485:2012	**MDD 93/42/AT**	**EN ISO 14971:2012**
EN ISO 15223-1:2012	**EN 1041:2008**	**EN ISO 14155:2011**
EN ISO 10993-7:2009	**EN ISO 62366:2008**	**EN 556-1:2001/AC:2006**
EN ISO 11135-1:2007	**EN ISO 11737-1:2006/AC:2009**	**EN ISO 11737-2:2009**
EN ISO 11607-1:2009	**EN ISO 11607-2:2006**	**EN ISO 10993-1:2009/AC:2010**
EN ISO 10993-5:2009	**EN ISO 10993-10:2009**	**EN 980:2008**

ŞEHİR, DÜZENLEME TARİHİ : **İSTANBUL / 04.01.2022**
PLACE, DATE OF ISSUE

İMZA/ *SIGNATURE* : **TARIK ALP SARI**
GENEL MÜDÜR
GENERAL MANAGER

EC Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

This is to certify that following IVD (In-Vitro Diagnostics) products:

Labosel and Debooglu and Debomed plastic medical and laboratory consumables listed in the attached Device Schedule,

Classified as: 'all other IVD Medical Devices' according to Annex I rules,

Manufactured by: **Debooğlu Inş. Mim. Tar. Ve Gıda A.Ş.**
Antakya Organized Industrial Zone, Cakallı Mah. 14 Nolu Yol, No:1 Belen, Hatay, Turkey, 31350

1. Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
2. Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:
   a. Availability of the thechnical documentation set in Annex III (section 3), allowing the assessment of the conformity of the product with the requirements of the Directive.
   b. The manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate fort he products manufactured (Annex III section 4).
   c. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).
3. Debooğlu A.Ş. has a Quality System in place based on ISO 13485:2016
4. This Declaration of Conformity is signed below, certifying that the requirements of Annex I and Annex III have been met and documented.

Authorised Representative: Debooğlu Ins. Mim. Tar. Ve Gıda AS
Antakya Organized Industrial Zone, Cakallı Mah. 14 Nolu Yol,
No:1 Belen, Hatay, Turkey, 31350
Tel: +90 533 680 0888

debooglu
İNŞAAT MİMARLIK TARIM ve GIDA ANONİM ŞİRKETİ
Çakallı Mah. 14 No.lu Yol Cad. No: 1 Belen / Hatay
T: +90 533 680 08 88 Belen VD: 272 081 0801
Mersis No.: 0272 0810 8600 0001

Date: 11.01.2022

.....
Mehmet H. Debooğlu
General Manager (Bsc Engineering)

Debooğlu A.Ş.

Device Schedule

Labosel™ and DebMed™ includes the following consumables.

Name	Detail
Automatic Pipette Tips	Yellow: 5 – 200 uL, Blue: 100 – 1000 uL
Microcentrifuge Tube (Eppendorf)	1.5 mL, with lid
Test Tube (Polystyrene)	5 mL 12x75 mm cylindrical bottom
Test Tube (Polystyrene)	10 mL 16x100 mL conical bottom
Test Tube Caps	For 12x75 mm and 16x100 mm tubes
Urine Specimen Containers	Sterile and Non-Sterile
Urine Specimen Containers	With Pochette and Not sterilized
Gaita/Stool/Faeces Containers	With spoon and screw cap, Sterile and Non-Sterile
Gaita/Stool/Faeces Containers	50 mL, pink
Centrifuge Tube (Falcon Tube)	15 mL, screw cap, Polypropylenec, Sterile and Non-Sterile
End of Schedule	

debooğlu
İNŞAAT MİMARLIK TARIM VE GIDA ANONİM ŞİRKET
Çakallı Mah. 14 No.lu Yol Cad. No: 1 Bey Hatay
T:+90 533 680 08 88 Bilen VD: 272 061 0861
Mersis No.: 0272 0810 8600 0001