



SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS



CE ATTESTATION OF CONFORMITY

**Related Directives :**  
**MEDICAL DEVICES 93/42/EEC-----TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC**

**Class / Sınıf: CLASS 1 / SINIF 1, NON STERILE**

**Description of Product :**  
**MEDICAL GOWNS**  
**TIBBİ ÖNLÜK**

**Product Model / Ürün Modeli:**  
\_PROTECTIVE GOWN, PATIENT GOWN, VISITOR GOWN, BOX GOWN, SURGICAL GOWN, DOCTOR'S GOWN  
KORUYUCU ÖNLÜK, HASTA ÖNLÜĞÜ, ZİYARETÇİ ÖNLÜĞÜ, BOX ÖNLÜĞÜ, AMELİYAT ÖNLÜĞÜ, DOKTOR ÖNLÜĞÜ

**Trade Mark / Ticari Marka: OPİA**

**Manufactured by**  
**GÖK OĞUZ MADENCİLİK SANAYİ VE TİCARET LİMİTED ŞİRKETİ**  
İSMET PAŞA MAH. TRABZON BLV. MİLCAN APT. SİT. NO:16/10  
DULKADİROĞLU / KAHRAMANMARAŞ / TÜRKİYE

**Certificate No.: SISTURCE10202097059**  
**Issue Date (Original): 12.10.2020**  
**Issue Date(Latest): 12.10.2020**  
**Expiry Date: 11.10.2021**



**This Certificate is issued under the following conditions:**

- 1.It applies only to the above referenced models of the medical devices.
- 2.It does not imply that the SIS has performed any surveillance or control of their manufacture.
- 3.The manufacture is obligated to assure conformity of all in medical devices of the respective model to type assessed by the mean of this certificate.
- 4.The certificate remains valid until the manufacturing condition, the quality system or relevant legislation are changed .
- 5.After fulfilling of the relevant EU legislation requirements, the manufacture shall affix to each medical device, of the above referenced models, the CE-marketing according to this example:

  
*Managing Director*



**Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.**

The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Compliance is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid.

Corporate office(SIS):- Plot No. 1539, 2nd Floor, Sector-4,Gurgaon-122001, Haryana, India.  
International office(SIS):- URB. Santa Ana Cal. German, Scherieber 276, San Isidro, Lima, Peru 15047.  
Email us :-arun@siscertifications.us, info@siscertifications.co.in. Call:- 0124-4060495  
Web:- <http://www.siscertifications.co.in>, [www.siscertifications.com](http://www.siscertifications.com)  
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Issue No.: 01

**CERTIFICATE OF COMPLIANCE**





SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS



CE ATTESTATION OF CONFORMITY

Related Directives :

MEDICAL DEVICES 93/42/EEC-----TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC

Class / Sınıf: CLASS 1 / SINIF 1, NON STERILE

Description of Product :

PROTECTIVE OVERALLS

KORUYUCU TULUM

Product Model / Ürün Modeli:

\_DISPOSABLE, NONWOVEN, LAMINATED BREATHABLE, WATER / FIRE REPELLENT, ANTIBACTERIAL HOODED, MEDICAL OVERALLS, DISINFECTION OVERALLS, LAMINATED OVERALLS, TYWEK OVERALLS, WATERPROOF OVERALLS, VISITOR OVERALLS, SPRAYING OVERALLS

TEK KULLANIMLIK, NONWOVEN, LAMİNE KAPLI NEFES ALABİLEN, SU / ATEŞ İTİCİ, ANTİBAKTERİYEL KAPŞONLU, MEDİKAL TULUM, DEZENFEKSİYON TULUMLARI, LAMİNE TULUM, TYWEK TULUM, SU GEÇİRMEZ TULUM, ZİYARETÇİ TULUMLARI, İLAÇLAMA TULUMLARI

Trade Mark / Ticari Marka: OPİA

Manufactured by

GÖK OĞUZ MADENCİLİK SANAYİ VE TİCARET LİMİTED ŞİRKETİ

İSMET PAŞA MAH. TRABZON BLV. MİLCAN APT. SİT. NO:16/10

DULKADİROĞLU / KAHRAMANMARAŞ / TÜRKİYE

Certificate No.: SISTURCE10202012615

Issue Date (Original): 12.10.2020

Issue Date(Latest): 12.10.2020

Expiry Date: 11.10.2021



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Managing Director



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Web:- <http://www.siscertifications.co.in>, [www.siscertifications.com](http://www.siscertifications.com)  
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CERTIFICATE OF COMPLIANCE





SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS



CE ATTESTATION OF CONFORMITY

Related Directives :  
MEDICAL DEVICES 93/42/EEC-----TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC

Class / Sınıf: CLASS 1 / SINIF 1, NON STERILE

Description of Product :

3 LAYER MEDICAL MASK

3 KATLI TIBBİ MASKE

Product Model / Ürün Modeli:

\_WHITE, BLUE, GREEN

BEYAZ, MAVİ, YEŞİL

Trade Mark / Ticari Marka: OPİA

Manufactured by

GÖK OĞUZ MADENCİLİK SANAYİ VE TİCARET LİMİTED ŞİRKETİ

İSMET PAŞA MAH. TRABZON BLV. MİLCAN APT. SİT. NO:16/10

DULKADİROĞLU / KAHRAMANMARAŞ / TÜRKİYE

Certificate No.: SISTURCE10202091250

Issue Date (Original): 12.10.2020

Issue Date(Latest): 12.10.2020

Expiry Date: 11.10.2021



This Certificate is issued under the following conditions:

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Managing Director



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Issue No.: 01

CERTIFICATE OF COMPLIANCE







SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS



## CE ATTESTATION OF CONFORMITY

### Related Directives :

**PERSONAL PROTECTIVE EQUIPMENT (PPE) DIRECTIVE 2016/425 (EU)**  
**KİŞİSEL KORUYUCU DONANIM YÖNETMELİĞİ 2016/425 (EU)**

**Class / Sınıf: CATEGORY 1 / KATEGORİ 1**

### Description of Product :

**PROTECTIVE OVERALLS**  
**KORUYUCU TULUM**

### Product Model / Ürün Modeli:

MEDICAL OVERALLS, DISINFECTION OVERALLS, LAMINATED OVERALLS, TYWEK OVERALLS,  
VISITOR OVERALLS, DISINFESTATION OVERALLS  
MEDİKAL TULUM, DEZENFEKSİYON TULUMLARI, LAMİNE TULUM, TYWEK TULUM,  
ZİYARETÇİ TULUMLARI, İLAÇLAMA TULUMLARI

### Trade Mark / Ticari Marka: OPİA

### Regulations Applied acc. To Harmonized Standards / Uygulanan Uyumlaştırılmış Standartlar:

EN 14126 Koruyucu giyecekler - Patojen organizmalara karşı  
EN ISO 13688 Koruyucu giyecekler-Genel özellikler  
TS EN ISO 22612 Bulaşıcılara karşı koruma için giysiler  
EN 14605 Koruyucu giyecekler - Sıvı kimyasal maddelere karşı - Vücudun sadece bir kısmına koruma  
sağlayanlar (tip pb [3] ve tip pb [4]) dâhil, bağlantı yerleri sıvı geçirmez (tip 3) veya sprey geçirmez (tip 4)  
giyecekler için performans özellikleri

### Manufactured by

**GÖK OĞUZ MADENCİLİK SANAYİ VE TİCARET LİMİTED ŞİRKETİ**  
İSMET PAŞA MAH. TRABZON BLV. MİLCAN APT. SİT. NO:16/10 DULKADİROĞLU / KAHRAMANMARAŞ / TÜRKİYE

**Certificate No.: SISTURCE10202087234**

**Issue Date (Original): 12.10.2020**


**Issue Date(Latest): 12.10.2020**

**Expiry Date: 11.10.2021**



### This Certificate is issued under the following conditions:

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Issue No.: 01

**CERTIFICATE OF COMPLIANCE**





October 20,2020

## 510(K) CLEARANCE SUMMARY

**Name and address:** GOK OGUZ MADENCILIK SANAYI VE TIC.LTD.STI  
Trabzon Bulvari Milcan Apt. No:16/10 Dulkadiroglu/  
KAHRAMANMARAS 46100

**Contact Person:** Ibrahim AKGUL

**Phone Number:** +905320151420

**Name of device:** GOK OGUZ MADENCILIK SANAYI VE TIC.LTD.STI

**Classification Name:** Gowns and Coverall

**510(k) Number 10075031**

**Dated:** September 20,2020

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.



U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

Sincerely,

**Andrew I. Steen-S**

For: Srinivas Nandkumar, Ph.D.  
Director

DHT1B: Division of Dental Devices  
OHT1: Office of Ophthalmic, Anesthesia,  
Respiratory, ENT and Dental Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



# CERTIFICATE of Registration



*This is to Certify that the  
Medical Devices – Quality Management System*

*of*

## **GÖK OĞUZ MADENCİLİK SANAYİ VE TİCARET LİMİTED ŞİRKETİ**

**İSMET PAŞA MAH. TRABZON BLV. MİLCAN APT. SİT. NO:16/10  
DULKADİROĞLU / KAHRAMANMARAŞ / TÜRKİYE**

**has been independently assessed and is compliant  
with the requirements of**

### **ISO 13485:2016**

**This Certificate is applicable to the following product or service ranges:**

PRODUCTION OF 1-PLY DISPOSABLE SURGICAL FACE MASK, 2-PLY DISPOSABLE SURGICAL FACE MASK, 3-PLY DISPOSABLE SURGICAL FACE MASK, N95 TYPE MASK, FFP1, FFP2 AND FFP3 TYPE VALVE NAD NON-VALVE MASK, DISPOSABLE PROTECTIVE COVERALL, DISPOSABLE ISOLATION/SURGICAL GOWNS, DISPOSABLE SURGICAL COVERS, DISPOSABLE EXAMINATION COVERS, DISPOSABLE BONNET, DISPOSABLE SHOE COVER, DISPOSABLE STRETCHER COVER, BODY BAG, GLOVES, WET WIPES, VISOR, GLASSES, 100 ML AND 1 LITER LIQUID DISINFECTANT, WITH WOVEN WOMEN OUTHWEAR AND DIGITAL PRINTING TEXTILE PRODUCTS, OCCUPATIONAL SAFETY DRESSES

TEK KULLANIMLIK TEK KATLI CERRAHİ MASKE, TEK KULLANIMLIK İKİ KATLI CERRAHİ MASKE, TEK KULLANIMLIK ÜÇ KATLI CERRAHİ MASKE, N95 TİP MASKE, FFP1, FFP2 VE FFP3 TİP VENTİLLİ VE VENTİLSİZ MASKE, TEK KULLANIMLIK KORUYUCU TULUM, TEK KULLANIMLIK CERRAHİ ÖNLÜK, TEK KULLANIMLIK CERRAHİ ÖRTÜ, TEK KULLANIMLIK MUAYENE ÖRTÜLERİ, TEK KULLANIMLIK BONE, TEK KULLANIMLIK GALOŞ, TEK KULLANIMLIK SEDYE ÖRTÜSÜ, CESET TORBASİ, ELDİVEN, ISLAK MENDİL, SİPERLİK, GÖZLÜK, 100ML VE 1 LİTRELİK SIVI DEZENFEKTAN İLE DOKUMA BAYAN DIŞ GİYİM VE DİJİTAL BASKI VE TEKSTİL ÜRÜNLERİNİN, İŞ GÜVENLİĞİ ELBİSELERİNİN ÜRETİMİ

**:: Certificate No :: TR52525H**

**Date of initial registration 02 June 2020**

**Date of this Certificate 02 June 2020**

**Surveillance audit on or before 01 June 2021**

**Recertification Due / Certificate expiry 01 June 2023**

This Certificate is property of Staunchly Management & System Services Ltd. and remains valid subject to satisfactory surveillance audits.

**Director**

**STAUNCHLY MANAGEMENT & SYSTEM SERVICES LTD.**

Suite 48, 88-90 Hatton Garden, London, EC1N 8PN.

**Phone : +44 345 680 0199**

**Email : info@staunchlyservices.com Web : www.staunchlyservices.com**

**SMS/F109A/17/REV02**

**For precise and updated information concerning the present certificate mail to info@staunchlyservices.com**

**This Certificate is the property of Staunchly Management & System Services Private Limited and shall be returned immediately when demanded**



Test Report

Test Owner name / address UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES TRADE CO.  
Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Umraniye, İstanbul /  
TURKEY

Manufacturer name/address GÖKOĞUZ MADENCİLİK SANAYİ VE TİCARET LTD. ŞTİ

Name and identity of the test item Protective Clothes

The date of receipt of the test item 28.07.2020

Brand name – model -

Date of the test 29.07.2020

Sample Number GTTS-0041-1, GTTS-0041-2, GTTS-0041-3

Number of pages of the report 8

GCNTR ULUS.BELG.GÖZ.EĞT.VE DIŞ.TİC.LTD.ŞTİ accredited by TÜRKAK under registration number AB-1272-T for EN ISO17025 as test laboratory".

The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.

Date/Seal  
29.07.2020

Head of Testing Laboratory  
Sebahattin CAY



This report only applies to the sample tested.

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Report No: GTL-TLM-0041/20

Test Report

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Report No: GTL-TLM-0041/20



Test Report

1. Documentation

1.1 Description of the EUT

All samples tested

Test samples subject to the test

Product Name	Samples No	Sample Size	Type	Application Tests
Protective Clothing	GTTS-0041-1	Medium	Type 6	Pre-exercise Test- Spray Test
Protective Clothing	GTTS-0041-2	Medium	Type 6	Pre-exercise Test- Spray Test
Protective Clothing	GTTS-0041-3	Medium	Type 6	Pre-exercise Test-Spray Test

1.2 Environmental Condition, Symbol Definitions

- Test case does not apply to the test object .....: N/A
- Test object meets the requirement.....: P (Pass)
- Test object does not meet the requirement.... : F (Fail)
- Environmental Conditions: °C , % RH, m/s

1.3 Test Standards

EN 13034+A1:2011 Protective clothing against liquid chemicals – Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment).



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Test Report

2. Test Result

Clause	Requirement	Result – Remark	Verdict
<b>4.3.2</b>	<b>Pre-Conditioning</b> Prior to testing, the chemical protective clothing shall be cleaned, if the manufacturer's instructions indicate that cleaning is allowed. Manufacturer's instructions with regard to number of cleaning cycles, cleaning procedures and possible reapplication of treatments shall be observed. If no maximum number of cleaning cycles is indicated, the clothing shall undergo five cleaning cycles.	Protective clothing are, it's was come in the form of plastic packing by the company. For this reason, no additional cleaning was performed with the suggestion of the company.	PASS
<b>4.3.3</b>	<b>Conditioning</b> All chemical protective clothing shall be conditioned for at least 24 h at the same conditions as used for the test.	All products are conditioned at 24 C° 50% Rh values for 24 hours.	PASS
<b>4.3.4</b>	<b>Resistance to the penetration of liquids</b>		
<b>4.3.4.1</b>	<b>General and Pre-test</b>		
	<b>Pre-Test</b>	In the exercise test deformations were seen in the sample M size. Deformation details is given in the figure 1.	PASS
<b>4.3.4.2</b>	<b>Resistance to the penetration of liquids (SprayTest)</b>	<b>Type 6</b>	
EN ISO 17491-4 Article 9	Remove respirator and gloves first before opening the test garment. Remove the chemical protective clothing carefully in order to avoid contamination of the absorbent overall and examine the internal surface of the test garment for signs of penetration, paying special attention to openings, seams, closures and zippers. Mark them.	Three test clothes were dressed tested together with the white absorbent underwear.  Region passing of liquid are given in figure 1.	PASS
Clouse 4.3.3.2 (Continued)	Any underwear, of each garment suit The total stain area on it should not be more than three times the calibrated total stain area.	Calibration stain area: measured as 4.56 cm². sum of stains on the inner white garment are given in table 2	PASS

This report only applies to the sample tested.

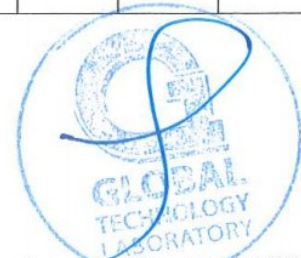
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Test Report

Table 1

Clause	Requirement	Pre-Experiment		Liquid Experiment 1		Liquid Experiment 2		Liquid Experiment 3	
		PASS	FAİL	PASS	FAİL	PASS	FAİL	PASS	FAİL
	Starting from a standing position in each case, carry out the following movement sequence:								
Movement 1	Kneel on both knees, lean forward and place both hands on the floor ( $45 \pm 5$ ) cm in front of the knees; crawl forward and backwards on hands and knees for a distance of three metres in each direction;	✓		✓		✓		✓	
Movement 2	Climb a vertical ladder at least four steps, rungs to be as encountered on a typical ladder;	✓		✓		✓		✓	
Movement 3	Position hands at chest level, palms out; reach directly overhead, interlock thumbs, extend arms fully upwards;	✓		✓		✓		✓	
Movement 4	Kneel on right knee, place left foot on floor with left knee bent ( $90 \pm 10$ ) °; touch thumb of right hand to toe of left shoe. Repeat movement with alternate posture, i.e. by kneeling on left knee and placing the right foot on the floor with knee bent at 90 °.	✓		✓		✓		✓	
Movement 5	Extend arms fully in front of body, lock thumbs together, twist upper body ( $90 \pm 10$ ) ° left and right;	✓		✓		✓		✓	
Movement 6	Stand with feet shoulder width apart, arms at side; raise arms until they are parallel to the floor in front of the body; squat down as far as possible;	✓		✓		✓		✓	
Movement 7	Kneel as in movement 4, left arm hanging loosely at side; raise arm fully overhead. Repeat movement with alternate posture by alternating arms.	✓		✓		✓		✓	



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Test Report

Pre-experiment 1	i.Ç Height: 180 cm Weight: 65 kg
Liquid Experiment 1	i.Ç
Liquid Experiment 2	i.Ç
Liquid Experiment 3	i.Ç

Table 2

SPREY EXPERIENCE						
	UPPER BODY			LOWER BODY		SUM
	Chest (cm <sup>2</sup> )	Shoulder (cm <sup>2</sup> )	Back (cm <sup>2</sup> )	Front (cm <sup>2</sup> )	Back (cm <sup>2</sup> )	
GTTS-0041						
Sample 1	0,3	0,2	12	-	-	12,5
Sample 2	-	0,5	11,2	-	-	11,7
Sample 3	-	-	12,8	-	-	12,8



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Test Report

3. Attachments

3.1 Photos of EUT



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Report No: GTL-TLM-0041/20



Test Report

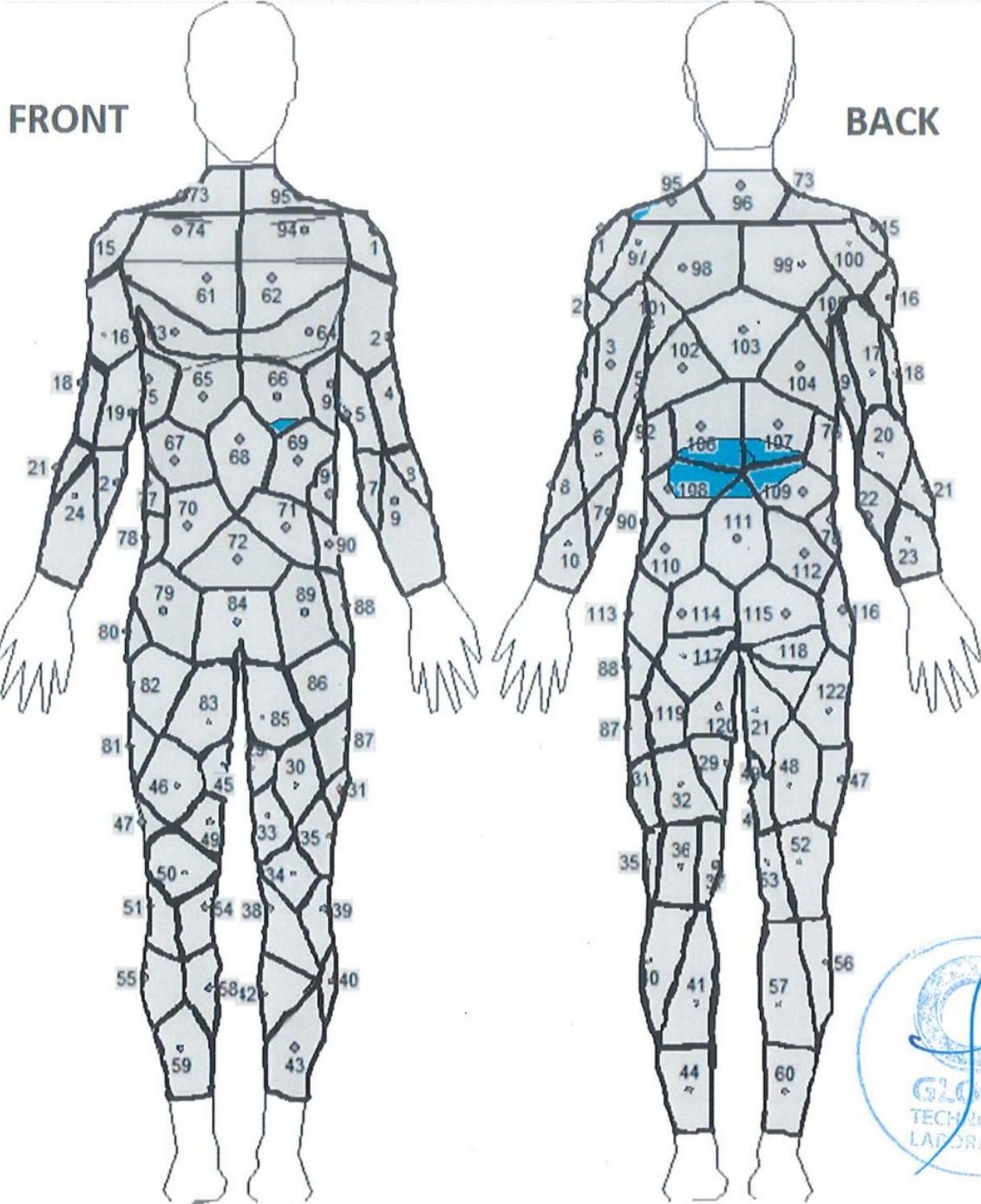


Figure 1 Region passing liquid

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