ISO 9001
KALİTE YÖNETİM SİSTEM BELGESİ

(TÜRKÇE)

Technical Universal Verification

CERTIFICATE

Bu Kalite Yönetim Sistem Sertifikası:

NİNOVA NÖROTEKNOLOJİ ARAŞTIRMA GELİŞTİRME SAN. VE TİC. LTD. ŞTİ.

KONAK MAH. ÜNİVERSİTE BULVARI NO:127/1 ŞAHİNBEY

GAZİANTEP - TÜRKİYE

Firmasının Kalite Yönetim Sisteminin Uygunluğunu belgelemek amacıyla verilmiştir. Sertifika,

ISO 9001 : 2015

Standardı ve Aşağıdaki Yönetim Sistemi Kapsamı İçin Geçerlidir.

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CERRAHİ EL ALETLERİNİN ÜRETİMİ, SATIŞI, PAZARLANMASI, İTHALAT VE İHRACATI

Sertifika No : 1301
Denetim Tarihi : 19.03.2020
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Yeniden Basım Tarihi : -
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FR 32/02.04.2020/REV.04

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PRODUCTION, SALES, MARKETING, EXPORT AND IMPORT OF
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PROTECTORS, SURGICAL COVERS AND APRONS, SURGICAL HAND TOOLS

Certificate No : 1301
Date of Audit : 19.03.2020
Date of Registration : 14.05.2020

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Expiry Date : 13.05.2021

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ISO 13485
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ISO 13485 : 2016

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CERRAHİ EL ALETLERİNİN ÜRETİMİ, SATIŞI, PAZARLANMASI, İTHALAT VE İHRACATI

Sertifika No : 4175
Denetim Tarihi : 19.03.2020
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Geçerlilik Tarihi : 13.05.2021

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MANAGEMENT SYSTEM
ISO/IEC 17021-1:2015
NAC-011-MS

FR 32/02.04.2020/REV.04

ISO 13485
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NAC-011-MS

FR 32/02.04.2020/REV.04

AB
UYGUNLUK
BEYANI

CE

EC DECLARATION OF CONFORMITY
AT UYGUNLUK BEYANI

Üretici Manufacturer: NİNOVA NÖROTEKNOLOJİ ARAŞTIRMA GELİŞTİRME SAN.VE TİC.LTD.ŞTİ.
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Telefon / Phone: +90 342 336 36 20
Email : info@ninova.io

ÜRÜN İSMİ VE TİPLERİ / PRODUCT NAME AND TYPES

KORUYUCU ÖNLÜK / PROTECTIVE GOWN -CERRAHİ ÖNLÜK (TEK KULLANIMLIK) / SURGICAL GOWN/DISPOSABLE) HASTA ÖNLÜĞÜ / PATIENT GOWN - ZİYARETÇİ ÖNLÜĞÜ / VISITOR APRON -BOX ONLOGO/BOX APRON - AMELİYAT ÖNLÜĞÜ / SURGICAL GOWN- DOKTOR ÖNLÜĞÜ/DOCTOR GOWN CERRAHİ ÖNLÜK / SURGICAL GOWN

BEYAN/STATEMENT

Burada, AB tarafından sınıflandırılan Üretici,Dağıtıcı ve Temsilci olarak kendi sorumluluğumuzun altında, yukarıda ismi ve modeli geçen ürünlerin, 93/42/EEC Tıbbi Cihaz Direktifi ve yönetmeliklerine ve EK-1 Temel Gereklere uygun olarak gerektiğini beyan ederiz.

Here, we declare that the products listed above are manufactured under our own responsibility as a Manufacturer,Distributor / Representative by the EU, in accordance with the 93/42/EEC Medical Device Directive and regulations.

ÜRÜNÜN MARKASI / PRODUCT BRAND

NiNOVA

DİREKTİF VE YÖNETMELİKLER / DIRECTIVES AND REGULATIONS

93/42/EEC Tibbi Cihaz Direktifi /9342/EEC Medical Device Directive

HARMONİZE STANDARTLAR / HARMONIZED STANDARDS

93/42/EEC- Tıbbi Cihaz Yönetmeliği SINIF I (Steril Olmayan) Medical Devices Regulation / Class I (Non Sterile)
TS EN 13795-1 Cerrahi Giysiler Ve Örtüler - Gereklilikler Ve Deney Yöntemleri - Bolüm 1: Cerrahi Örtüler Ve Önlükler Surgical Clothing And Drapes - Requirement And Test Methods - Part 1: Surgical Drapes And Gowns
TS EN ISO 13485 Tıbbi Cihazlar - Kalite Yönetim Sistemleri - Düzenleyici Amaçlar için Gereklilikler Medical Devices - Quality Management Systems - Requirements For Regulatory Purposes
TS EN ISO 15223-1 Tıbbi Cihazlar - Tıbbi Cihaz Etiketlerinde. Etiketlemede ve Sunulacak Bilgide Kullanlacak Semboller - Bölüm 1: Genel Gerekler / Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling And Information To Be Supplied - Part 1:General Requirements
TS EN 1041+A1 Tıbbi Cihaz İmalatçıları Tarafından Sağlanan Bilgiler / Information Supplied By The Manufacturer Of Medical

Sertifika Tarihi /Certificate Date: 22.05.2020
Sertifika Bitiş Tarihi /Certificate Expiration Date: 22.05.2021

Accredited System Certification Approval

CERTIFICATE / ZERTIFIKAT / СВИДЕТЕЛЬСТВО / СЕРТИФИКАТ / CERTIFICATO / CERTIFIKÁ

EN 13795

NİNOVA NÖROTEKNOLOJİ

ARAŞTIRMA GELİŞTİRME SAN.VE TİC.LTD.ŞTİ.

Regulated in accordance with the EU Directive 93/42 / EEC on Medical Devices

EU Declaration of Conformity

Producer:	NİNOVA NÖROTEKNOLOJİ ARAŞTIRMA GELİŞTİRME SAN.VE TİC.LTD.ŞTİ. San, Tic. Ltd. Şti.
Address:	KONAK MAH. ÜNİVERSİTE BLV. 127/1 ŞAHİNBEY/GAZİANTEP/ TÜRKİYE
Name of the product:	Ninova Gown
Product description:	The product is designed as sterile surgical gowns.
Applied Directives:	Directive 93/42 / EEC on medical devices. conformity assessment Annex VII According to (Class I sterile device)
Compliance Standards Applied:	EN 13795-1

NİNOVA NÖROTEKNOLOJİ ARAŞTIRMA GELİŞTİRME SAN.VE TİC.LTD.ŞTİ. hereby declares that the product mentioned above is in compliance with all applicable provisions of Directive 92/42 / EEC. The product is safe under prescribed and reasonably predictable storage and usage conditions.

The company implements measures to ensure the safety of products of the above-mentioned type and their compliance with the essential requirements of Directive 93/42 / EEC.Has established a systematic procedure to implement appropriate methods for then ensures that it stays.

The company has established a systematic procedure to review the experience gained from the devices at the post-production stage and apply appropriate methods for the necessary corrective actions, and ensures that this procedure remains up to date. The company notifies technical or medical reasons that cause the product to be withdrawn by the manufacturer, as well as defects or defects in product qualities or performance, or deficiencies in the instructions for use, or deficiencies in the instructions for use, to the Competent Authority, undertakes.

In case of a change in the product without the approval of the authorized signatory below, this declaration becomes invalid for the replacement product.

Issued: June 12, 2020

Halil Ahmet Yaman
General Manager

NİNOVA NÖROTEKNOLOJİ ARAŞTIRMA GELİŞTİRME SAN.VE TİC.LTD.ŞTİ
(SIGNATURE)

SURGICAL COVER AND GOWNS-EN 13795-1

SPECIFICATION	TEST METHOD	UNIT	SURGICAL GOWNS				SURGICAL DRAPES			
			STANDART PERFORMANCE		HIGH PERFORMANCE		STANDART PERFORMANCE		HIGH PERFORMANCE	
			CRITICAL AREA	MORE LESS	CRITICAL AREA	MORE LESS	CRITICAL AREA	MORE LESS	CRITICAL AREA	MORE LESS
Microbial Penatration- Dry	EN ISO 22612	Kob	NOT NECESSARY	≤300	NOT NECESSARY	≤300	NOT NECESSARY	≤300	NOT NECESSARY	≤300
Microbial Penatration- Wet	EN ISO 22610	I_s	≥2,8	NOT NECESSARY	6,0	NOT NECESSARY	≥2,8	NOT NECESSARY	6,0	NOT NECESSARY
Microbial Cleaning/ Bioburden	EN ISO 11737-1	Kob/ 100 cm_2	≤300	≤300	≤300	≤300	≤300	≤300	≤300	≤300
Particle Release	EN ISO 9073-10	Log (fiber count)	≤4,0	≤4,0	≤4,0	≤4,0	≤4,0	≤4,0	≤4,0	≤4,0
			≥20	≥10	≥100	≥10	≥30	≥10	≥100	≥10
Liquid Penetration	EN ISO 811	Cm H_2O	≥40	≥40	≥40	≥40	≥40	≥40	≥40	≥40
Burst Strength-Dry	EN ISO 13938-1	kPa								
Burst Strength-Wet	EN ISO 13938-1	kPa	≥40	NOT NECESSARY	≥40	NOT NECESSARY	≥40	NOT NECESSARY	≥40	NOT NECESSARY
Breaking Strength-Dry	EN ISO 29073-3	N	≥20	≥20	≥20	≥20	≥15	≥15	≥20	≥20
Breaking Strength-Wet	EN ISO 29073-3	N	≥20	NOT NECESSARY	≥20	NOT NECESSARY	≥15	NOT NECESSARY	≥20	NOT NECESSARY

Requirements for surgical drapes and gowns are determined according to EN 13795-1 standard.

EN ISO 11737-1

Microbial
(Bioburden)

EN ISO 29073-3
Stitch Strength
(Wet / dry)

EN ISO 13938-1
Burst Strength

EN ISO 811
Liquid Penatration

EN ISO 22610

Microbial
Penetration
(Wet)

TESTING ORGANIZATION MAKING TESTS.
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TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES

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Report No:	2020070825
Applicant:	**NİNOVA NÖROTEKNOLOJİ ARAŞTIRMA GELİŞTİRME SAN. Ve TİC.LTD. ŞTİ.** Konak mah. Üniversite bulvarı 127/1 Şahinbey/ Gaziantep
Contact Person:	Halil Ahmet YAMAN
Contact Telephone:	0345 336 3620 / 0532 375 9260
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Sample Accepted on:	24.06.2020
Report Date:	08.07.2020
Total number of pages:	7 (Pg)

Sample ID: **Cerrahi Önlük 35 gr sms nonwoven kumaştan üretilmiş / Surgical Gown Made of 35 gr sms nonwoven fabric**

	TEST	METHOD	Specimen	RESULT
*	**Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Part 1: General requirements for manufacturers, processors and products**	**EN 13795-1**	**Surgical Gown Made of 35 gr sms nonwoven fabric**	**PASS** **Maximum Performance**

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş. TÜRCERT

Seal

Customer Representative
Hasan KUTLU

EUROLAB LABORATUVAR HİZMETLERİ İTH. İHR. LTD. ŞTİ.

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Environment

The requirements and standards apply to equipment intended for use in

X	Residential (domestic) environment
X	Commercial and light-industrial environment
X	Industrial environment
X	Medical environment

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EN 13795-1 Inspection Test Report

This standard specifies information to be supplied to users and third party verifiers, in addition to the usual labelling of medical devices (see EN 980 and EN 1041), concerning manufacturing and processing requirements.

TEST RESULTS (WHITE)

Dry Penetration Testing

Talc contaminated with spores is poured onto the test piece inside a container. The platform supporting the container is vibrated by a pneumatic ball vibrator. Any talc that has penetrated through will be captured on an agar plate. The agar plate is incubated, and the total number of colonies on the surface the plate are counted.

The mean bacterial count is calculated and compliance with the performance requirements determined.

In this test, a portion of talc contaminated with a known number of Bacillus subtilis (B. atrophaeus) spores are poured onto the test piece inside a container. A container without the contaminated talc is used as the control. An agar plate is inserted into the base of the container below the test piece. The platform supporting the container is vibrated for 30 minutes by a pneumatic ball vibrator. Any talc that has penetrated through the test piece will be captured by the agar plate. The agar plate is then removed and incubated for 24 hours at 35°C and the total number of colonies on the surface the plate are counted.

The mean bacterial count is calculated and compliance with the performance requirements determined.

Dry Penetration

EN ISO 22612		
12 hours	71 cfu	PASS
24 hours	96 cfu	

Dry Penetration	
Class 2/3	Penetration Low

End of test.

Resistance to wet microbial penetration (mechanical contact)

Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration

The standard defines the procedure for testing a material's resistance to wet bacterial penetration. The test method involves challenging the bacterial-contaminated(Staphylococcus Aureus) donor material of 10 micron HDPE onto the test barrier material, placed on an agar plate and subjecting it to mechanical rubbing. Any penetration through the material is cultured and measured on an agar plate against a control. There are six classes, as defined in the standard, with their corresponding breakthrough times, indicating the point at which the bacteria measurably penetrate the barrier material.

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Resistance to wet microbial penetration

EN ISO 22610			
1	< 15 min	No penetration	PASS 5/6
2	> 15 min	No penetration	
3	> 30 min	No penetration	
4	> 45 min	No penetration	
5	> 60 min	No penetration	
6	> 75 min	Fail	

Wet Penetration	
Class 6/6	5/6

End of test.

Microbial cleanliness (Bioburden)

When tested according to EN ISO 11737-1 the bioburden of the medical gown shall be ≤ 30 cfu/g tested.
To determine the fabric's bioburden according to EN ISO 11737-1, follow the procedure below:
The number of fabrics that shall be tested is minimum 5 (five), but can be greater if necessary to allow for an AQL of 4 %. Weigh each fabric prior testing. The full fabric is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl & 2 g/l polysorbate surfactant 20 [e.g. Tween 20, Alkest TW 20]). The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 µ filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30 °C and 7 days at (20 – 25) °C for TSA and SDA plates respectively.
The total bioburden is expressed by addition of the TSA and SDA counts.
In the report, indicate the total bioburden per fabric and based on the fabric weigh, the total bioburden per gram tested.

Test	**Limit**	**Result**	**Evaluation**
Remark	EN ISO 11737-1		
Microbial cleanliness (cfu/100 cm^2)	≤ 200	51	PASS

End of test.

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Cleanliness – Particulate Matter / Linting

Textiles — Test methods for nonwovens — Part 10: Lint and other particles generation in the dry state

A tube was made from one of the test pieces so the longer dimension corresponded to the circumference and the free edges glued on an approximate 0.5 cm width. The sample tube was carefully attached to the circular plates of the flex tester. The plates were set to a starting position of 188 ± 2 mm apart and the flexing chamber door elosed. The laser partide counter and flexing unit were started. Ten continuous 30 second periods were recorded and each partide size channel recorded. After testing, the flexing unit and partide counter were stopped.

The sample was removed and the chamber cleaned as deseribed in the "Test Controls" seetion of this report. The procedure was repeated for ali ten samples, five from side A and five from side B.

SMS GOWN with absorbent reinforcement

Period (sec.)	Particulate Size (pm)						TOTAL LİNTİNG	
	0.3	0.5	1.0	5.0	10.0	25.0	>0.3	>0.5
30	95	93	92	29	24	29	298	275
60	33	31	23	6	2	3	77	74
90	13	12	14	2	1	1	43	38
120	18	18	18	1	0	1	45	37
150	9	13	16	2	1	0	42	36
180	15	14	19	2	0	0	35	32
210	9	13	13	1	1	0	38	29
240	11	13	25	1	1	0	57	41
270	9	13	17	2	0	0	46	34
300	7	11	19	1	1	0	36	32
Total	213	214	255	41	29	34	788	576
Total - C0	213	213	254	41	29	34	771	573
Std Dev	60	80	140	16	9	17	296	243
Coef of Var	29	38	56	40	31	50	36	47
						Coe of Linting:	2.97	2.98

End of test.

Resistance to Liquid Penetration – Hydrostatic Head Test

EN 20811 Tested in accordance with the Long-Tail test method manual

Note: Deviation from test procedure: Sampling in accordance with customer requirement. Testing was carried out in a Standard Temperate atmosphere

The water pressure was applied from below the test specimen. The water pressure was increased at 60.0 cm water/min.

The Inner to Outer of the fabric was tested.

Sample 1	Description Area	Measurable sample status.	Results
1	No Inner Soaker	>100cm	110 cm/H_2O
2	No Inner Soaker	>100cm	110 cm/H_2O

End of test.

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Bursting Strength

EN ISO 13938 Textiles- Bursting properties of fabrics- Part 1: Hydraulic method for determination of bursting strength and bursting distension

This standard, describes a hydraulic pressure method for the determination of bursting strength and bursting distension of textile fabrics.

Remark	Mean Burst (kPA)	Mean height at burst (mm)
DRY	129	25
WET	134	25

End of test.

Tensile Strength

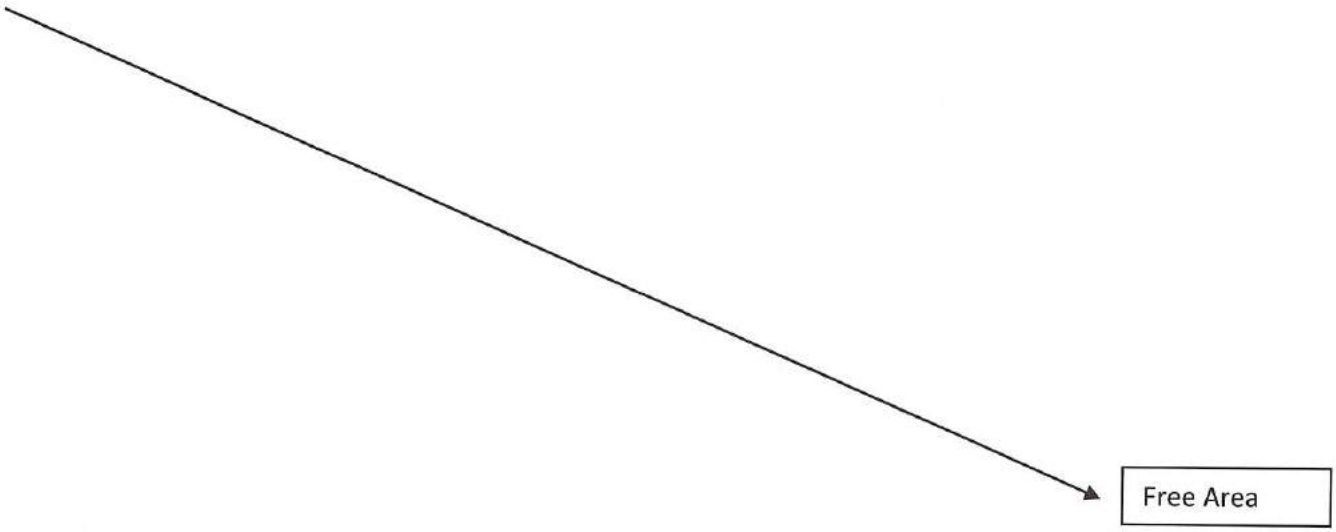
EN 29073-3 Textiles-Test Methods For Nonwovens Part 3- Determination Of Tensile Strength And Elongation

This standard specifies a method for the determination of the tensile propurties of nonwovens by the out strip method.

Remark	Mean Value [N]*	maximum elongation [%]
DRY	88	27
WET	91	27

End of test.

Conclusion: Maximum Performance



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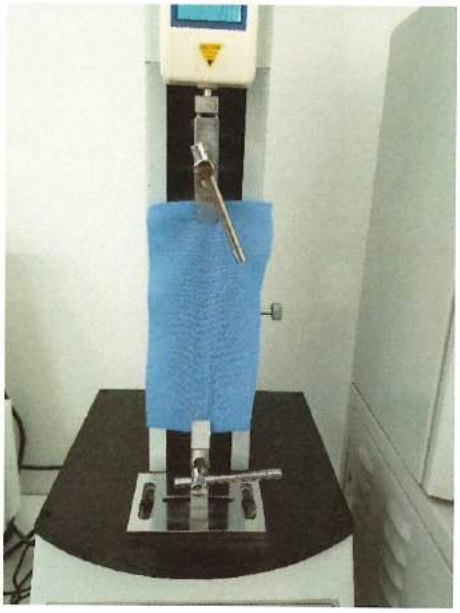
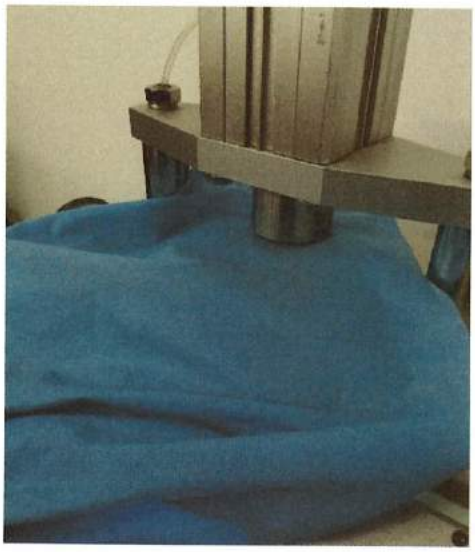
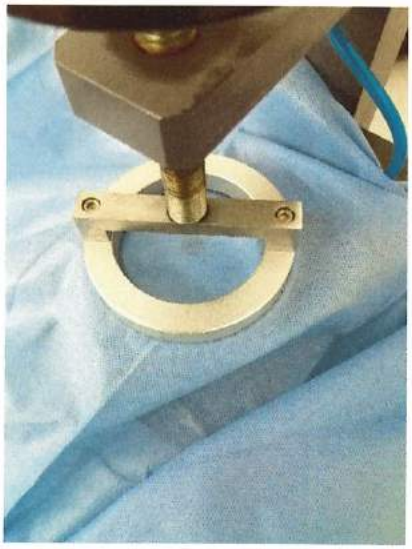
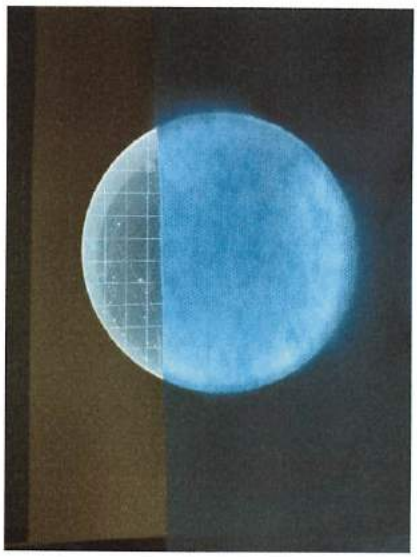
IMAGES UNDER TEST









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EN 14126

TEST REPORT DECLARATION

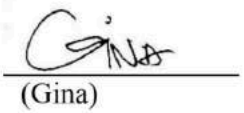
Applicant	:NINOVA NOROTEKNOLOJI ARASTIRMA VE GELISTIRME SAN. VE TIC.LTD. STI
Address	:Konak Mah. Universite Bulv. 127/1 Sahinbey / Gaziantep /TURKEY
Manufacturer Address	:Konak Mah. Universite Bulv. 127/1 Sahinbey / Gaziantep /TURKEY
EUT Description	:NINOVA GOWN
Model No.	:001
Remark	:N/A

Test Procedure Used:
EN 14126:2003+AC:2004, EN ISO 13982-1:2004+A1:2010

The test results of this report relate only to the tested sample identified in this report.

Date of Test 22 / 06 / 2020

Prepared by  (Jack)

Checked by  (Gina)

Approved by  (Johnson)

PPE TEST REPORT

For

NINOVA NOROTEKNOLOJI
ARASTIRMA VE GELISTIRME SAN. VE TIC. LTD. STI

Prepared By : Modern Testing Services (Global) Ltd
Modern Testing Services (International) Ltd By Ekoteks

Unit 808, CEO Tower, 77 Wing Hong Street
Cheung Sha Wan, Kowloon, Hong Kong

Date of Test: 22/06/2020
Date of Report: 28/06/2020

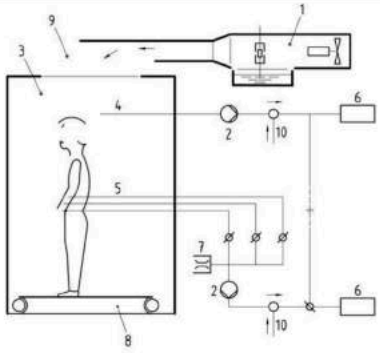
EN 14126:2003+AC:2004			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
1	Scope		P
	This European Standard specifies requirements and test methods for re-usable and limited use protective clothing providing protection against infective agents. Clothing worn by surgical teams or drapes laid on patients to prevent cross-contamination during surgical interventions are not covered by the scope of this standard.		P
2	Normative references		P
	This European standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).		P
3	Terms and definitions		P
	For the purposes of this European Standard, the terms and definitions of prCEN ISO/TR 11610:2003 and the following terms and definitions apply.		P
4	Requirements		P
4.1	Materials requirements		P
	4.1.1 General If the care instructions indicate that the clothing can be cleaned and reprocessed at least five times, protective clothing materials shall be submitted to five cleaning and reprocessing cycles according to the manufacturer's care instructions before testing. If the care instructions specify a lower number of cleaning/reprocessing cycles, then materials shall be submitted to the number of cleaning/reprocessing cycles indicated. Unless otherwise stated in the relevant test procedure, the specimens shall be conditioned for at least 24 h in an atmosphere of (20 ±2) °C and (65 ±5) % relative humidity before testing. Tests shall be carried out in the same atmosphere or within 5 min of removing the sample from the conditioning atmosphere.		P
	4.1.2 Mechanical and flammability requirements The materials shall be tested and classified in		P

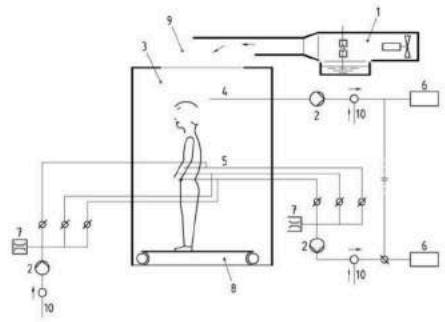
EN 14126:2003+AC:2004			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
	accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.		
	4.1.3 Chemical requirements If protection against chemicals is claimed, the materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.		P
	4.1.4 Performance requirements against penetration by infective agents 4.1.4.1 Resistance to penetration by contaminated liquids under hydrostatic pressure When tested in accordance with ISO/FDIS 16603 and ISO/FDIS 16604 the material shall be classified according to the levels of performance given in Table 1, as obtained in the bacteriophage test (ISO/FDIS 16604).		P
	Table 1 — Classification of resistance to penetration by contaminated liquids under hydrostatic pressure (ISO/FDIS 16604) Class | Hydrostatic pressure at which the material passes the test 6 | 20 kPa 5 | 14 kPa 4 | 7 kPa 3 | 3,5 kPa 2 | 1,75 kPa 1 | 0 kPa [a] [a] this means that the material is only exposed to the hydrostatic pressure of the liquid in the test cell		
	4.1.4.2 Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids. When tested in accordance with Annex A the material shall be classified according to the levels of performance given in Table 2.		P
	Table 2 — Classification of resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids **Class** | **Breakthrough time, *t* min** 6 | $t > 75$ 5 | $60 < t \leq 75$ 4 | $45 < t \leq 60$ 3 | $30 < t \leq 45$ 2 | $15 < t \leq 30$ 1 | ≤ 15 min		
	4.1.4.3 Resistance to penetration by contaminated		P

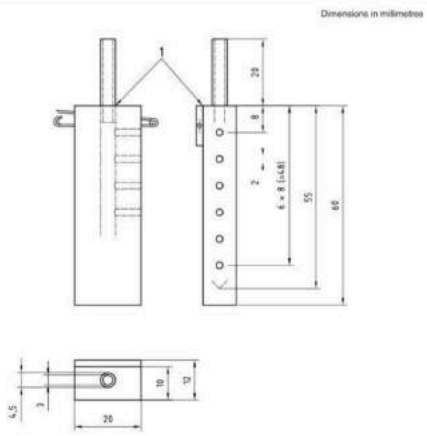
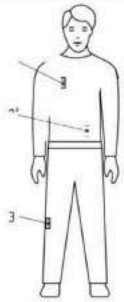
EN 14126:2003+AC:2004			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
	liquid aerosols When tested in accordance with ISO/DIS 22611 the material shall be classified according to the levels of performance given in Table 3.		
	Table 3 — Classification of resistance to penetration by contaminated liquid aerosols **Class** | **Penetration ratio (log)** 3 | log > 5 2 | 3 < log ≤ 5 1 | 1 < log ≤ 3		
	4.1.4.4 Resistance to penetration by contaminated solid particles. When tested in accordance with ISO/DIS 22612 the material shall be classified according to the levels of performance given in Table 4.		P
	Table 4 — Classification of resistance to penetration by contaminated solid particles Class | Penetration (log cfu) 3 | ≤ 1 2 | 1 < log cfu ≤ 2 1 | 2 < log cfu ≤ 3		
4.2	Performance requirements for seams, joins and assemblages		P
	Seams, joins and assemblages of protective clothing against infective agents shall fulfil the requirements specified in the relevant clauses of prEN 14325 Seam strength shall be classified according to 5.5 of prEN 14325:2001.		P
4.3	Whole suit requirements		P
	Protective clothing against infective agents shall fulfil the relevant requirements of EN 340 and the whole suit requirements specified in the relevant standard for chemical protective clothing (see Table 5). The materials and design used shall not cause skin irritation nor have any adverse effect to health.		P

EN 14126:2003+AC:2004			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
	Table 5 — Types of protective clothing against infective agents Type of clothing / Relevant standard type 1a, 1b, 1c, 2 — EN 943-1 (EN 943-2 for ET suits) type 3 — EN 466 type 4 — EN 465 type 5 — prEN ISO 13982-1 type 6 — prEN 13034 partial body protection — EN 467		P
5	Marking		P
	The clothing shall be marked in accordance with the applicable requirements of the relevant standard for chemical protective clothing. The marking of protective clothing against infective agents shall contain the following additional information: a) the number of this European Standard; b) the type of protective clothing, as specified in Table 5, with the suffix "-B", e.g. type 3-B; c) the pictogram "protection against biological hazard"		P
6	Information supplied by the manufacturer		P
	The information for the user shall be worded clearly and unambiguously and be understandable by a trained person. The information for the user of protective clothing against infective agents shall contain all the information required by EN 340 and by the relevant standard for that specific type of chemical protective clothing. In addition it shall contain the following information: a) the number of this European Standard; b) the type designation, e.g. type 3-B; c) the biological agents against which the protective clothing has been tested. This information shall be expressed as performance levels, as specified in 4.1.4.1 to 4.1.4.4 for the relevant types of biological challenge; d) all other relevant information on performance levels, preferably as a Table; e) the information necessary for trained persons about: application and limitations of use (temperature range, etc.); if relevant, checks to be carried out by the wearer before use; fitting and adjustments, and any accessories needed to provide the claimed level of protection; use; maintenance, cleaning and disinfection; storage; if relevant, a warning against problems likely to be encountered;		P

EN 14126:2003+AC:2004			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
	if relevant, illustrations, part numbers and marking of spare parts, etc. disposal after use.		

4	Principle		--
	A standard aerosol of sodium chloride particles is generated inside a test chamber in which a test subject, wearing the protective suit under test, carries out a predetermined sequence of test exercises. The inward leakage at each sampling position inside the suit is measured by means of flame photometry. The percentage inward leakage at each sampling position (L ijmn), the total inward leakage per suit (L S) and per test subject (L H), the total inward leakage per exercise (L E) and per sampling position (L P) and the mean total inward leakage (L) are calculated.		P
5	Apparatus		--
5.1	Aerosol generator, flame photometer(s), one or two, and a test chamber, as described in EN 136.		P
5.2	Level treadmill, capable of operating at (5 ? 0,5) km/h, which is installed inside the chamber. The test arrangement used for the determination of inward leakage is shown schematically in Figures 1 and 2.		P
	 Key 1 atomizer 2 pump 3 chamber 4 challenge sample 5 air lines to and from the suit (both sampling and feeding lines) 6 photometer 7 flow meter 8 treadmill 9 ducting and baffle 10 addition of dry, clean air Figure 1 — Test arrangement (schematic)		--

	 Key 1 atomizer 2 pump 3 chamber 4 challenge sample 5 air lines to and from the suit (both sampling and feeding lines) 6 photometer 7 flow meter 8 treadmill 9 ducting and baffle 10 addition of dry, clean air Figure 2 — Modified test arrangement for feeding additional dry, clean air into tubes close to the sampling probes (schematic)		--
5.3	Sodium chloride aerosol test agent, with a particlesize distribution, mean test-agent concentration and distribution inside the chamber as described in EN 136.		P
5.4	Adjustable pump and air lines, used for sampling air from the suit under test.		P
	This pump is adjusted to deliver a sampling flow rate from inside the suit in the range of (2 ? 0,5) l/min. The flow shall be kept constant within ? 0,2 l/min. Depending on the type of photometer, it may be necessary to dilute the sample air with clean air. There shall be no condensation in tubes during testing. Condensation in the tubes can be avoided by feeding dry, clean air directly into the tubes upstream of where condensation occurs (see Figure 2), by heating of the tubes or by any other suitable means. One should take the dilution into account when calculating the concentration at the sampling point.		P
5.5	Sampling probes, four, constructed as shown in Figure 3, one which shall be used to measure the challenge concentration and three, the concentration inside the suit. Each probe is fitted onto a length of suitable transparent plastic tube with an internal diameter of 4,0 mm.		P

	 Figure 3 — Sampling probe		--
	The three probes for measuring the concentration inside the suit shall be positioned close to the body of the test subject, at the following positions as shown in Figure 4:		P
	 Key 1 on the right chest 2 at the back of the waist 3 at knee height, lateral a Probe 2 is positioned on back. Figure 4 — Positions of the three sampling probes on body of test subject		--
	Especially in the case of two-piece suits and coveralls equipped with an elastic waistband or a belt worn over the suit, the positions of the sampling points should be carefully chosen. Sampling probes shall not be positioned directly onto the skin, but shall be fixed onto the underwear. The sampling lines to and from the sampling probes inside the suit shall be fixed close to the body of the test subject and shall pass through the material of the suit between 5 cm and 15 cm above one of the arm-cuffs in an airtight manner. The fixings of the sampling lines and the		P

	passthrough should have as little influence on the fit of the suit as possible and should not impair the		

	movements of the test subject. To ensure that there is no additional inward leakage into the suit, due to under-pressure created by extraction of the sample air, clean air shall be fed back into the suit at the same rate as sample air is pumped out, i.e. at (2 ? 0,5) l/min. This clean air shall be introduced through one of the other two sampling probes, according to the sequence of sampling given in Table 1. The necessary arrangements should be made to ensure that the air is injected in the right compartment of the suit, in particular in the case of two-piece suits or coveralls including a belt or elastic waistband, where there may be insufficient exchange of air between compartments.		
5.6	Sampling system for the challenge aerosol, separate from that sampling the test concentration in the suit, with a separate flame photometer if possible, in order to avoid contamination of the total inward leakage sampling lines. If a second photometer is not available, it is possible to determine the challenge concentration by a separate sampling system and the same photometer. However, sufficient time will then be required to allow the photometer to return to a stable background signal level before measuring total inward leakage.		P
6	Test procedure		--
6.1	Selection of test subjects		--
	For the test, persons shall be selected who are familiar with the use of this or similar protective equipment and whose medical history is known to be satisfactory. Before performing tests involving human subjects, account shall be taken of any national regulations concerning the medical history, examination or supervision of the test subject. The test subject shall wear close-fitting underwear (e.g. polyester/cotton long trousers and a T-shirt with long sleeves). The underwear shall be changed after each suit tested. The size of the suit shall be selected in accordance with the test subject's body dimensions and according to the manufacturer's instructions. Prior to the test, each suit shall be examined to ensure that it is in good working condition and that it can be used without hazard.		P
6.2	General test conditions		--

	At least five test subjects shall test at least two suits per person, i.e., at least ten suits shall be tested. The test subjects shall be asked to read the manufacturer's instructions and, if necessary, they shall be shown by the test supervisor how to wear the suit properly according to the instructions. The		P

	test subjects shall be informed that if they wish to adjust the suit during the test they may do so. If this is done, however, the relevant section of the test shall be repeated after sufficient time has elapsed for the system to stabilize. After putting on the suit, each test subject shall be asked: "Does the suit fit?" If the answer is "yes", proceed with the test. If the answer is "no", take the subject off the test panel, report the fact and replace the test subject by another. The test subjects shall be given no indication of the results as the test proceeds. If not otherwise specified, all tests shall be carried out at (20 ? 5) °C and a relative humidity inside the test chamber of less than 60 %. The test temperature and relative humidity inside the test chamber prior to the testing of each suit and at the end of all test exercises for each suit shall be recorded and reported.		
6.3	Test sequence		--

	The following test sequence shall be followed for each suit. -- Connect the tubing to the sampling points and dress the test subject in the suit, in accordance with the manufacturer's instructions. Ensure that the pass-through for the sampling tubes is as leaktight as possible. Let the test subject also put on additional equipment, such as boots, gloves, hood, mask, etc., in accordance with the manufacturer's instructions. If the manufacturer's instructions do not specify the need for additional equipment, then these should not be worn. However, the test subject may wear a suitable respiratory protective device, e.g. a filtering facepiece. In addition, if the manufacturer's instructions do not require the suit to be taped to any part of the body of the wearer (such as wrists and ankles) or to any additional item (e.g. gloves or boots) worn by the test subject, then these types of taping should not be done. It is recommended that all additional equipment be supplied by the manufacturer. -- Let the test subject enter the test chamber. -- Measure and report the concentration of the test agent before the generation of the aerosol inside the suit at all three sampling positions to ensure that, in all cases, the background concentration is at least one order of magnitude below the expected concentration during testing. If the background concentration is higher, investigate why and correct the problem. This may require preliminary testing. -- Start generating the test agent and allow the challenge concentration in the chamber to stabilize. Ensure that the test subject is standing still during this period. Measure and report the challenge concentration. If stabilization of		P

	challenge concentration in the chamber takes more than 1 min, the suit shall be ventilated to avoid penetration of particles into it. -- Measure the concentrations at the following sampling positions (see also Figure 4): -- knee (lateral), -- waist (back), -- chest (right); following the sampling sequence and the corresponding sequence of feeding clean air into the suit described in Table 1, whilst the test subject performs the test exercises in the following order: 1) standing still, 2) walking at 5 km/h, 3) continuous squatting at a frequency of five squats per minute, between standing up straight and knees completely bent, while keeping both hands during all squats on a grip at a height of (1 ? 0,05) m above the standing surface. Allow for a 3 min rest (standing still) between the walking and the squatting exercises. During the test sequence 4, "stabilization between walking and squatting", concentrations should be measured but do not need to be reported. The time for each exercise at each sampling position shall be 3 min. The average concentration over the last 100 s of each exercise and at each of the sampling points shall be calculated and reported. Measurement of the average concentration is preferably made using an integrating recorder. Where the same photometer is used to measure both the challenge and the penetrating sodium chloride concentrations, the challenge concentration shall be measured and reported at the completion of the test sequence. The challenge concentration at the end of all test exercises shall be within ? 10% of the initial challenge concentration. If this is not the case, the test results shall be discarded and the problem shall be corrected. -- Stop generating the test agent, disconnect the sample tubes and let the test subject leave the test chamber.		
7	Calculation of test results		--
7.1	Calculation of percentage inward leakage		--
	The percentage inward leakage, L ijmn , shall be calculated from measurements made over the last 100 s (to avoid carry-over of results from one exercise to the other) for each of the three sampling positions (n) for each of the three exercise periods (m) for each of the suits tested (j) (with at least two suits per test subject) for		P

	each of the test subjects (i) (at least five test subjects) in accordance with Equation (1):		
	$L_{ijmn} = \frac{C_{ijmn} \times 100\%}{C}$ where C is the challenge concentration; C_{ijmn} is the concentration for sampling position n for exercise m for suit j for test subject i. All percentage inward leakage values shall be reported.		--
7.2	Calculation of total inward leakage		--
7.2.1	The total inward leakage, L S,j , per suit for suit j, shall be calculated in accordance with Equation (2): $L_{S,j} = \frac{1}{mn} \sum_{m} \sum_{n} L_{ijmn}$ The data reported shall pertain to 10 results from 10 or more suits.		P
7.2.2	The total inward leakage, L H,i , per human subject for subject i shall be calculated in accordance with Equation (3) $L_{H,i} = \frac{1}{jmn} \sum_{j} \sum_{m} \sum_{n} L_{ijmn}$ The data reported shall pertain to 5 results from 5 or more subjects.		P
7.2.3	The total inward leakage, L E,m , per exercise for exercise m shall be calculated in accordance with Equation (4): $L_{E,m} = \frac{1}{jn} \sum_{j} \sum_{n} L_{ijmn}$ The data reported shall pertain to 3 results from 3 exercises.		P
7.2.4	The total inward leakage, L P,n , per position for test position n shall be calculated in accordance with Equation (5): $L_{P,n} = \frac{1}{jm} \sum_{j} \sum_{m} L_{ijmn}$ The data reported pertain to 3 results from 3 sampling positions.		P

7.2.5	The total inward leakage per position and per exercise, L EP , for exercise m and position n shall be calculated in accordance with Equation (6): $L_{EP,mn} = \frac{1}{j}\sum_{j} L_{ijmn}$ The data reported pertain to 10 suits (or more).		P
7.2.6	The mean total inward leakage The average, L of all total inward leakage measurements shall then be calculated in accordance with Equation (7) and reported: $\bar{L} = \frac{1}{j}\sum_{j} L_{S,j} = \frac{1}{i}\sum_{i} L_{H,i} = \frac{1}{m}\sum_{m} L_{E,m} = \frac{1}{n}\sum_{n} L_{P,n}$		
8	Test report		--
	The test report shall contain the following information: a) reference to this International Standard (i.e., ISO 13982-2:2004); b) identity of the manufacturer of the suit; c) size of the suits tested and the body measurements of the test subjects, in accordance with the provisions of EN 340; d) description of the underwear worn by test subjects; e) description of any pre-treatment and/or preconditioning of the suits tested, e.g. mechanical pre-stressing of suits for determining the durability of barrier efficiency; f) description of any additional protective equipment or any accessories worn during the test and if and how the accessories were taped to the suit; g) temperature and relative humidity inside the test chamber prior to the testing of each suit and at the end of all test exercises for each suit; h) concentration of test agent inside the suit at all three sampling positions for each suit prior to testing; concentration of test agent inside the test chamber after stabilizing the test agent concentration and at the end of all test exercises; i) all inward leakage results, presented in the form of data tables: -- tables giving the percentage inward leakage values L ijmn and averages per test subject and test suit (i.e., at least 10 tables modelled on Table 2), -- table giving total inward leakage values for all test subjects and test suits (modelled on Table 3), -- table giving total inward leakage values per test subject (modelled on Table 4); j) any comments considered appropriate by the person who has carried out the tests.		P

Table 1 — Sampling sequence for probes inside the suit during the period when the test subject is present in the chamber and during the sequence of activity

Measuring sequence		Timing min	Sampling through probe at position:	Feeding of clean air through probe at position:	Exercise
Number	Activity				
1	measuring the background inside suit (before generation of the aerosol)	—	knee	chest	standing still
		—	waist back	knee	
		—	chest	waist back	
2	waiting for stabilization and measuring the test agent concentration inside chamber	—	—	—	
3	measuring the test agent concentration inside suit	3	knee	chest	standing still
		3	waist back	knee	
		3	chest	waist back	
		3	knee	chest	walking
		3	waist back	knee	
		3	chest	waist back	
4	stabilization between walking and squatting	1	knee	chest	standing still
		1	waist back	knee	
		1	chest	waist back	
5	measuring the test agent concentration inside suit	3	knee	chest	squatting
		3	waist back	knee	
		3	chest	waist back	
6	measuring the test agent concentration inside chamber	—	—	—	standing still

Table 2 — Model for reporting inward leakage values, expressed in percent, of suit *j* worn by test subject *i*

Exercise	Sampling position/Feeding-in position			Average per exercise %
	Knee/Chest	Waist back/Knee	Chest/Waist back	
standing still	L_{ij11}	L_{ij12}	L_{ij13}	L_{E1ij}
walking	L_{ij21}	L_{ij22}	L_{ij23}	L_{E2ij}
squatting	L_{ij31}	L_{ij32}	L_{ij33}	L_{E3ij}
average per sampling position	L_{P1ij}	L_{P2ij}	L_{P3ij}	L_{Sij}

Table 3 — Model for reporting total inward leakage values, expressed in percent, per sampling position and per exercise (averaged over all suits)

Exercise	Sampling position/Feeding-in position			Average per exercise %
	Knee/Chest	Waist back/Knee	Chest/Waist back	
standing still	L_{EP11}	L_{EP12}	L_{EP13}	L_{E1}
walking	L_{EP21}	L_{EP22}	L_{EP23}	L_{E2}
squatting	L_{EP31}	L_{EP32}	L_{EP33}	L_{E3}
average per sampling position	L_{P1}	L_{P2}	L_{P3}	$\overline{L}$

Table 4 — Model for reporting total inward leakage values, expressed in percent, per test subject

Test subject	Total inward leakage per suit, L_{Sj}	Total inward leakage per human test subject, L_{Hi}
1	L_{S1}, L_{S2}	L_{H1}
2	L_{S3}, L_{S4}	L_{H2}
...*i*...	L_{S2i-1}, L_{S2i}	L_{Hi}
average	$\overline{L}$	$\overline{L}$

- End of Review Report -