Non-Sterile Isolation Gown

Specifications of Garment

- Non-woven fabric - %100 Polypropylene
- One size - REGULAR
- Water resistance
- Disposable/Single Use
- Suitable for hospital, dental and outpatient use
- Designed to protect the wearer against airbone bacteria or virus particles

Lightweight and comfortable functionality & mobility

Suitable for hospital, dental and outpatient use

Medical Use

Offers practical and dependable protection against fluids,particulates and other contaminants.

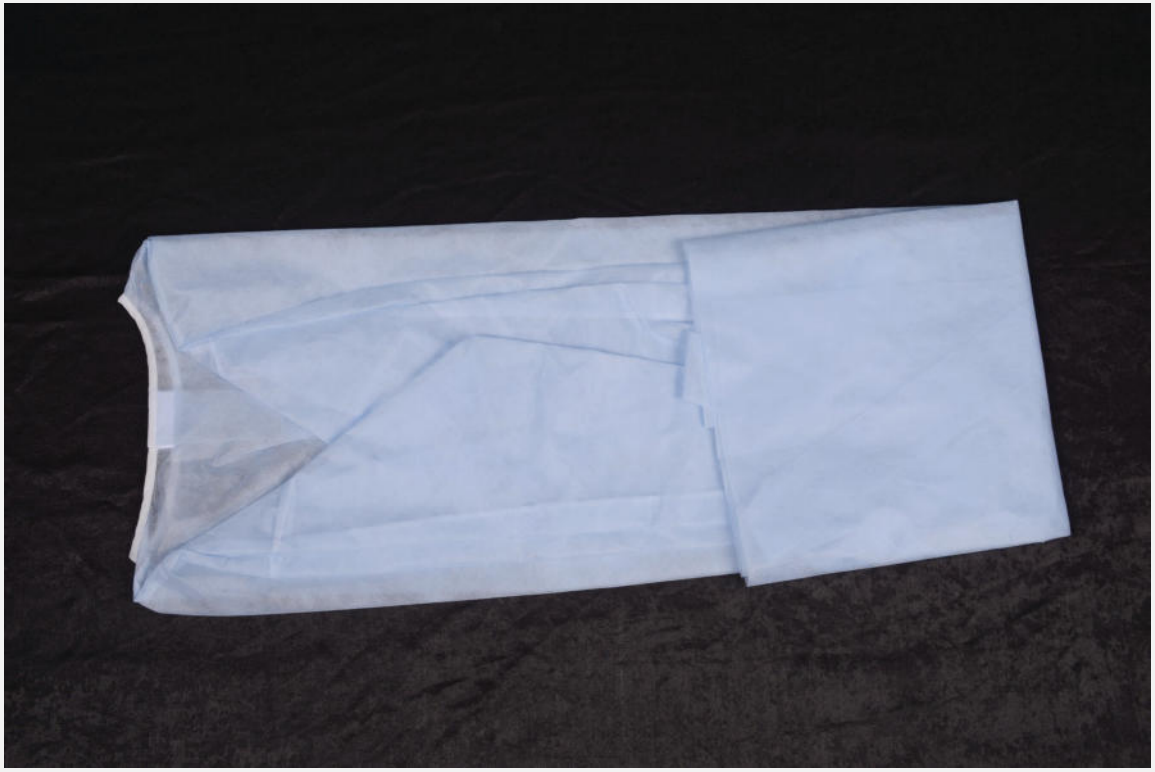
- safety
- protection
- health

Non-Sterile

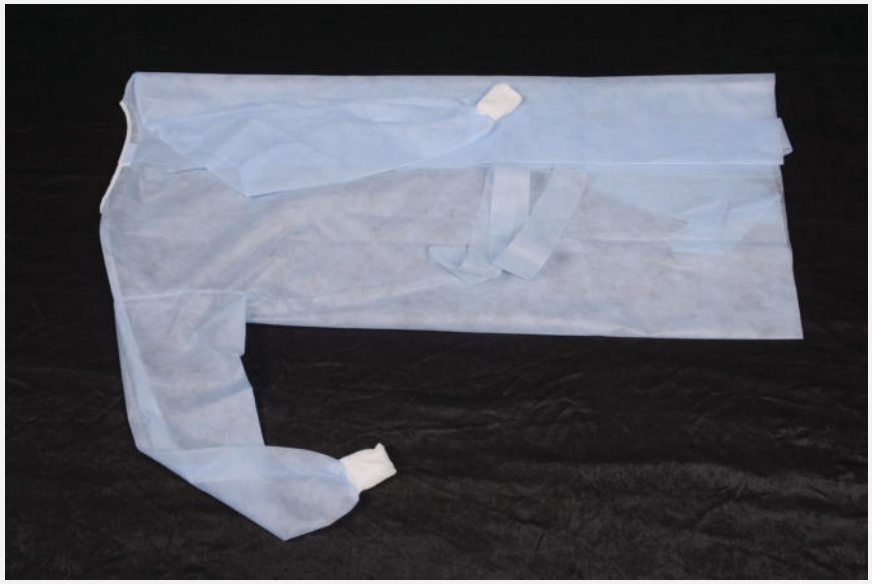
Isolation Gown

High quality spunbond material, strong and durable fabric
Elastic rib cuffs and one - piece suit design
Wide range of uses in hospitals, pharmacies, dental clinics,medical laboratories,
pet hospitals, beauty salons, research institutes.

PRODUCT PICTURES



PRODUCT PICTURES



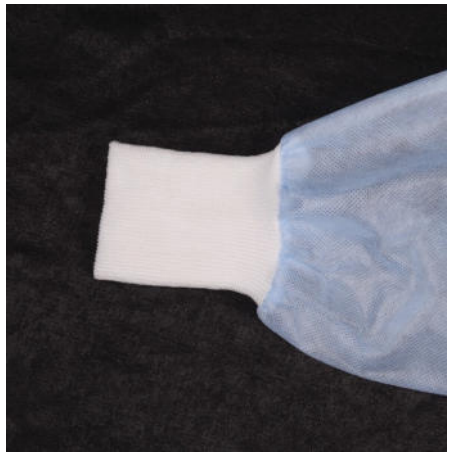
PRODUCT DESCRIPTION

VELCRO DESIGN

User friendly velcro design.

ELASTIC CUFFS

Comfortable rib knit cuffs for flexible usage.



DRAWSTRINGS

Ease of use for each and every body shape.

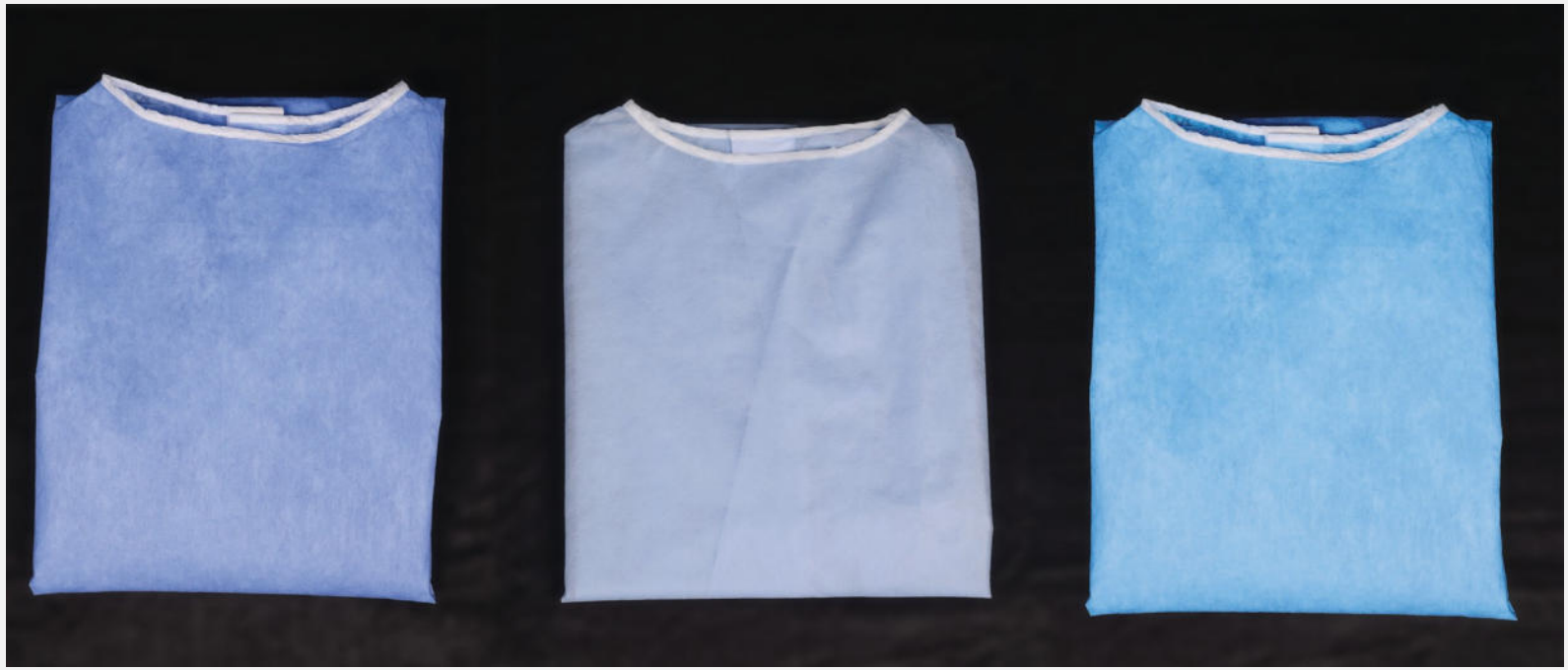
PHYSICAL PROPERTIES

Features & Benefits

Non sterile isolation gown fabric provides superior protection to dust and liquid jets along. Isolation gown offers the perfect comfort and durability expected. Fabric's material allows the moisture vapor to escape through the gown. The ergonomic style pattern allows much greater freedom of movement.

BONUS ADD-ON :
Breathable fabrics and ergonomic style pattern help to reduce the risk of heat stress.

According to the fabric production plan of the mills, colours can vary. Depends on the order confirmation, we will check and inform you about the colours.



PANTONE
Dark Blue

PANTONE
Sky Blue

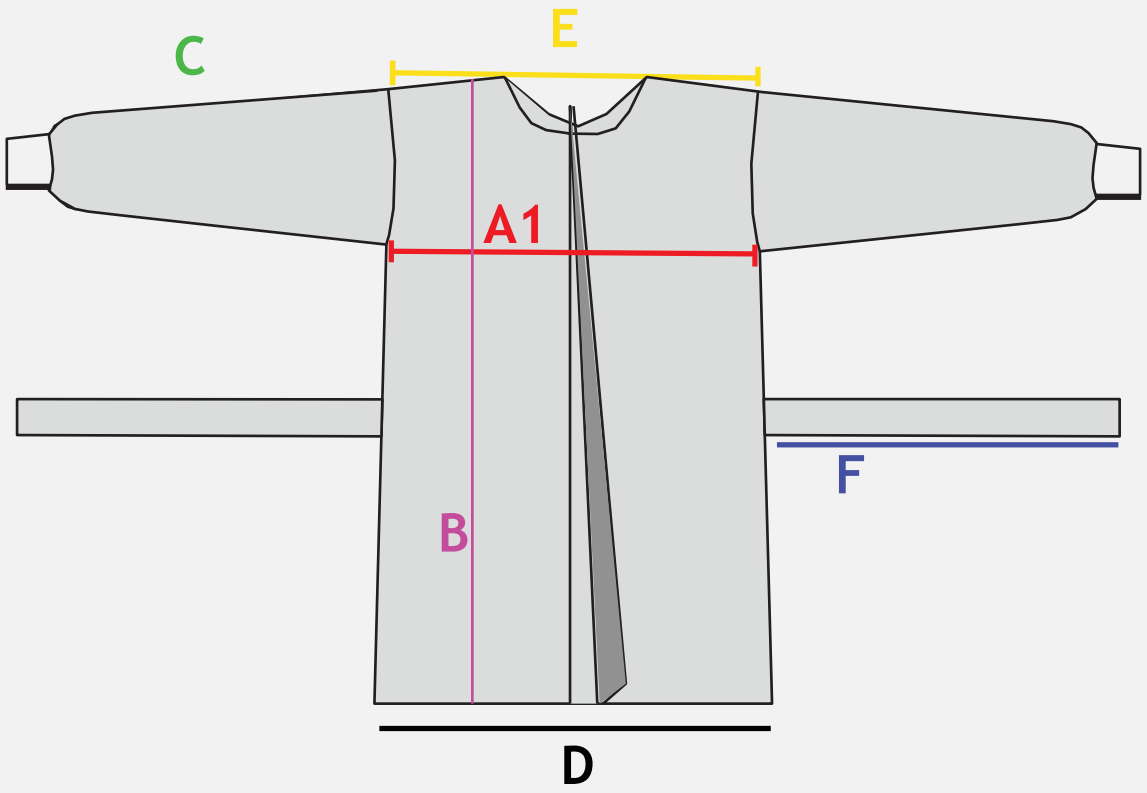
PANTONE
Light Blue

PRODUCT PICTURES

PRODUCT PICTURES

MEASUREMENTS OF GARMENT

A1	CHEST 1/2	73 cm
B	TOTAL LENGTH FROM SHOULDER	116 cm
C	TOTAL ARM LENGTH	65 cm
D	SWEEP	73 cm
E	SHOULDER TOSHOULDER	63 cm
F	TIE LENGTH	88 cm



CERTIFICATES

UNIVERSAL

UNIVERSAL
CERTIFICATION

CERTIFICATE

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LİMİTED ŞİRKETİ,

has established and applies a medical devices Management System for the activities below and it is certified according to UNIVERSAL CERTIFICATION procedures

" PRODUCTION AND SALES OF PROTECTIVE COVERALL, MEDICAL FACE MASKS, BODY BAG, GOWN, NURSE UNIFORM "
EA 04

BL.02563.20 numbered report prepared as a result of the audit carried out shows that the organization provided the requirements of

ISO 13485:2016

This certificate is valid until **04.05.2021**

Certificate Number: **20.02423**

First Date of Issue: **05.05.2020**, Recertification Date: -------, Date of Issue: **05.05.2020**

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
General Manager

Doğrulama kare kodu

The validity of this certificate is 3 years and depends on the success of the organization at the surveillance audit which will be held at least once a year. Certificate's status can be controlled from www.universalcert.com web site or verification of QR code.

UNIVERSAL

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CERTIFICATION

CERTIFICATE

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LİMİTED ŞİRKETİ,

has established and applies a Good Manufacturing Practices System for the activities below and it is certified according to UNIVERSAL CERTIFICATION procedures

" PRODUCTION AND SALES OF PROTECTIVE COVERALL, MEDICAL FACE MASKS, BODY BAG, GOWN, NURSE UNIFORM "
EA 04

BL.02563.20 numbered report prepared as a result of the audit carried out shows that the organization provided the requirements of

GMP – GOOD MANUFACTURE PRACTICE

This certificate is valid until **04.05.2021**

Certificate Number: **20.02423-1**

First Date of Issue: **05.05.2020**, Recertification Date: -------, Date of Issue: **05.05.2020**

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
General Manager

Doğrulama kare kodu

The validity of this certificate is 3 years and depends on the success of the organization at the surveillance audit which will be held at least once a year. Certificate's status can be controlled from www.universalcert.com web site or verification of QR code.

CERTIFICATES

UNIVERSALCERT.COM

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ATTESTATION OF CONFORMITY

Certificate No: MDD - 109

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonisation of laws, regulations and administrative documentation of Member States on Medical Devices and European Economic Commission directive 93/68/EEC amending Medical Devices Directive dated 22 July 1993.

the products manufactured by

at the following address

EN 13795-1:2019 Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns

Brand Name:
Model: GOWN 100 Polypropilene Non-Sterile Disposable Isolation Gown
Model: GOWN 200 Polyestere Non-Sterile Disposable Isolation Gown
(Standard Performance)are tested according to the following initial type tests by the manufacturer

For the assessment of conformity, the following documents were also reviewed:
Laboratory test results for Microbial Penetration (wet/dry), Bioburden, Bursting and Tensile Strengths (wet/dry)

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the surgical gowns manufactured and designed for use to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, §13. of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; performance level and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 13/05/2020 and valid until 12/05/2021 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

ISTANBUL -13/05/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

This certificate will be in the absence of any changes in standard and legal terms, and with the surveillance audits to be executed annually following the surveillance audits, updating the publicationdate without changing the certificate number.

EU DECLARATION OF CONFORMITY

MANUFACTURER

PRODUCT DESCRIPTION

Brand Name:
Model: GOWN 100 Polypropilene Non-Sterile Disposable Isolation Gown
Model: GOWN 200 Polyestere Non-Sterile Disposable Isolation Gown
Surgical Gowns with standard performance to be used to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures, classified as Medical Device (Class I)

The Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely in accordance with the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- European Regulation (EU) 2017/745 and 93/42/EEC Medical Devices Directive establishing technical requirements for medical devices, in effective wording
- Technical standard EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
- Other relevant harmonized legislation and standards
- For the assessment of conformity, the following documents were also applied to:
- Results of laboratory tests for Microbial Penetration – Dry by National Protective Testing LLC
- Results of laboratory tests for Microbial Penetration - Wet and Microbial Cleanliness, Bioburden by Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş.
- Results of laboratory tests for Bursting and Tensile Strengths (wet/dry) by Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş.

MARKING, LABELLING

Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the surgical gown is supplied. The information supplied with the product considering EN ISO 15223-1:2016 and EN 1041:2008+A1:2013.

MEASURES TO ENSURE CONFORMITY

The Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

CE

General Manager
13/05/2020

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Form LG.044/Rev.0

TÜRKAK
Test
TS EN ISO/IEC 17025
AB-0716-T

AB-0716-T
TURT200061245
05-20

TEST REPORT

REPORT NUMBER : **TURT200061245**
APPLICANT NAME :
ADDRESS :

Attention :
SAMPLE DESCRIPTION : One sample of Blue non sterile medical gown
DATE IN : **4 May ,2020 (13:59:00)**
RESUBMIT DATE : **11 May ,2020**
DATE OUT : **12 May ,2020**
BUYER'S NAME :
BUYER'S REGION : EUROPE
MODEL/ STYLE NO :
FIBER COMPOSITION : Claimed to be 100% Polypropylen

Burcu KESKİNSOY KUNDAKÇI
Customer Care Executive

Zeynep AKIN
Chemical Laboratory Manager

Intertek Test Hizmetleri A.S.
Merkez Mahallesi Sanayi Cad. No.23 Altindag Plaza Yenibosna-34197 /ISTANBUL
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http://www.intertek-turkey.com

200061245

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AB-0716-T

TEST REPORT

REPORT : TURT200061245

TEST	SAMPLE 1
Determination of Alkylphenolethoxylates (APEO) for Textile	NR
Determination of Cadmium Content	P
Determination of Certain Aromatic Amines Derived from Azo Colorants	P
Determination of Free and Hydrolised Formaldehyde Test (Water extraction method)	NR
Determination of Polychlorophenols	P
Polycyclic Aromatic Hydrocarbons (PAHs) Analysis	P
Total Lead in Non Metal Products	P

P = MEETS BUYER' S REQUIREMENT / F = DOES NOT MEET BUYER' S REQUIREMENT / NR = NO REQUIREMENT / SC=STILL CONTINUES / X=NOT PERFORMED / NA = NOT APPLICABLE / LS = LACK OF SAMPLE / NC = NO COMMENT / I = INCONCLUSIVE / # = SEE RESULT / NF = NEEDS FURTHER TESTING / A = ABSENT / M = MARGINAL ACCEPT / SD = SEE DETAILS ENCLOSED / FS: FURTHER STEPS

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e-mail : intertekcg.turkiye@intertek.com
http://www.intertek-turkey.com

200061245

Test Method	Results	Requirements

Determination of Alkylphenolethoxylates (APEO) for Textile

BS EN ISO 18254-1:2016

Determination of APEO by Liquid Chromotography-Mass Spectrometry (LC-MS-MS) Analysis

Blue interlining, white sleeve part, white trim

Alkylphenols		
Nonylphenol (NP)	Not Detected	No Requirement
Octylphenol (OP)	Not Detected	
Alkylphenol Ethoxylates		
Nonylphenolethoxylates (NPEO)	Not Detected	No Requirement
Octylphenolethoxylates (OPEO)	Not Detected	

ppm = mg/kg
Detection Limit = 50 ppm
ND = not detected

Determination of Alkylphenolethoxylates (APEO) for Textile

BS EN ISO 18254-1:2016

Determination of APEO by Liquid Chromotography-Mass Spectrometry (LC-MS-MS) Analysis

White loop

Alkylphenols		
Nonylphenol (NP)	Not Detected	No Requirement
Octylphenol (OP)	Not Detected	
Alkylphenol Ethoxylates		
Nonylphenolethoxylates (NPEO)	Not Detected	No Requirement
Octylphenolethoxylates (OPEO)	Not Detected	

ppm = mg/kg
Detection Limit = 50 ppm
ND = not detected

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Test Method	Results	Requirements

Determination of Cadmium Content

BS EN 1122 : 2001 (Method B)

Determination by microwave digestion and ICP -OES

White velcro	<5 ppm	100 ppm (0.01%)

ppm (part per million) =mg / kg Detection Limit =5 ppm < =Less Than
% =Percentage based on dry weight of sample
REMARK As per Cadmium Content Requirement in Annex XVII item 23 of the REACH Regulation (EC) No:1907/2006 (Formerly Known as Directive 91/338/EEC), Acid Digestion Method was used Total Cadmium Content was determined by ICP-OES

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Test Method	Results	Requirements

Determination of Certain Aromatic Amines Derived from Azo Colorants

EN ISO 14362-1:2017

By Gas Chromatographic - Mass Spectrometric (GC-MS) And High Performance Liquid Chromatographic (HPLC) Analysis.

1-Blue interlining (with extraction) <30 ppm

		RESULTS
FORBIDDEN AMINE	**CAS NO**	**1**
4-AMINOBIPHENYL	92-67-1	N
BENZIDINE	92-87-5	N
CHLORO-O-4-CHLOR-O-TOLUIDINE	95-69-2	N
2-NAPHTHYLAMINE	91-59-8	N
*O-AMINOAZOTOLUENE	97-56-3	N
*2-AMINO-4-NITROTOLUENE	99-55-8	N
P-CHLOROANILINE	106-47-8	N
2,4-DIAMINOANISOLE	615-05-4	N
4,4'-DIAMINOBIPHENYLMETHANE	101-77-9	N
3,3'-DICHLOROBENZIDINE	91-94-1	N
3,3'-DIMETHOXYBENZIDINE	119-90-4	N
3,3'-DIMETHYLBENZIDINE	119-93-7	N
3,3'-DİMETHYL-4,4' DIAMINOBIPHENYLMETHANE	838-88-0	N
P-CRESIDINE	120-71-8	N
4,4'-METHYLENE-BIS-(2 CHLOROANILINE)	101-14-4	N
4,4'-OXYDIANILINE	101-80-4	N
4,4'-THIODIANILINE	139-65-1	N
O-TOLUIDINE	95-53-4	N
2,4-TOLUENEDIAMINE	95-80-7	N
2,4,5-TRIMETHYLANILINE	137-17-7	N
O-ANISIDINE	90-04-0	N
**P-AMINOAZOBENZENE	60-09-3	N
2,4 XYLIDINE	95-68-1	N
2,6 XYLIDINE	87-62-7	N

Note:
1)The amines o-amino-azotoluene and 2-amino-4-nitrotoluene are detected by its splitted product o-toluidine and 2,4- toluenediamine.
2)Azo colorants that are able to form 4-aminoazobenzene, generate under the condition of this method aniline and 1,4- phenylendiamine . The presence of these colorants can not be reliably ascertained without additional information, e.g. chemical structure of the colorant used.
3)According to ISO 14362-1:2017, separate test is suggested to ascertain the compliance for result of mixed test in the range between 5 ppm and 30 ppm.
4)Azocolourants Content Requirement In Annex XVII Item 43 Of The REACH Regulation (EC) NO. 1907/2006 & Amendment No. 552/2009 and 126/2013 (Formerly Known As Directive 2002/61/EC
5) According to the official method ISO 14362-1:2017, if 4-Aminodiphenyl or 2-Naphthylamine or 2,4-Diaminoanisole is found exceeding requirement, the use of forbidden Azo colourants cannot be ascertained without additional information e.g. The chemical structure of the colourant used.

ppm : part per million (mg/kg) Detection Limit: 5 ppm < = Less Than N: Not Detected NC : No Comment

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Test Method	Results	Requirements

Determination of Free and Hydrolised Formaldehyde Test (Water extraction method)

BS EN ISO 14184 - 1 :2011 Free and Hydrolized Formaldehyde by UV-VIS Analysis

Blue interlining, white sleeve part, white trim	Not Detected	No Requirement
White loop	Not Detected	

ppm (part per million) =mg / kg
Detection Limit =5 ppm
< =Less Than
Note :Sample was received unsealed

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Test Method	Results	Requirements

Determination of Polychlorophenols

BVL B 82.02-8:2001-06

Blue interlining, white sleeve part, white trim	Result	Requirement
Pentachlorophenol (PCP)	Not Detected	0.5 ppm
Tetrachlorophenol (TeCP)		0.5 ppm
2,3,4,5 Tetrachlorophenol	Not Detected	
2,3,4,6 Tetrachlorophenol	Not Detected	
2,3,5,6 Tetrachlorophenol	Not Detected	
Trichlorophenol (TriCP)		2 ppm
2,3,4 Trichlorophenol	Not Detected	
2,3,5 Trichlorophenol	Not Detected	
2,3,6 Trichlorophenol	Not Detected	
2,4,5 Trichlorophenol	Not Detected	
2,4,6 Trichlorophenol	Not Detected	
3,4,5 Trichlorophenol	Not Detected	
Dichlorophenol (DCP)		3 ppm
2,3- Dichlorophenol	Not Detected	
2,4- Dichlorophenol	Not Detected	
2,5- Dichlorophenol	Not Detected	
2,6- Dichlorophenol	Not Detected	
3,4- Dichlorophenol	Not Detected	
3,5- Dichlorophenol	Not Detected	
Monochlorophenols (MCP)		3 ppm
2-Chlorophenol	Not Detected	
3-Chlorophenol	Not Detected	
4-Chlorophenol	Not Detected	

ppm (part per million) =mg / kg Detection Limit = PCP, TeCP : 0.05 ppm (lower limit) or 0.5 ppm ; OPP : 0.5 ppm
< = Less Than ND = Not Detected
Remark : PCP Content Requirement in Annex XVII Item 22 of the Reach Regulation (EC) No : 1907/2006

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Test Method	Results	Requirements

Determination of Polychlorophenols

BVL B 82.02-8:2001-06

White loop	Result	Requirement
Pentachlorophenol (PCP)	Not Detected	0.5 ppm
Tetrachlorophenol (TeCP)		0.5 ppm
2,3,4,5 Tetrachlorophenol	Not Detected	
2,3,4,6 Tetrachlorophenol	Not Detected	
2,3,5,6 Tetrachlorophenol	Not Detected	
Trichlorophenol (TriCP)		2 ppm
2,3,4 Trichlorophenol	Not Detected	
2,3,5 Trichlorophenol	Not Detected	
2,3,6 Trichlorophenol	Not Detected	
2,4,5 Trichlorophenol	Not Detected	
2,4,6 Trichlorophenol	Not Detected	
3,4,5 Trichlorophenol	Not Detected	
Dichlorophenol (DCP)		3 ppm
2,3- Dichlorophenol	Not Detected	
2,4- Dichlorophenol	Not Detected	
2,5- Dichlorophenol	Not Detected	
2,6- Dichlorophenol	Not Detected	
3,4- Dichlorophenol	Not Detected	
3,5- Dichlorophenol	Not Detected	
Monochlorophenols (MCP)		3 ppm
2-Chlorophenol	Not Detected	
3-Chlorophenol	Not Detected	
4-Chlorophenol	Not Detected	

ppm (part per million) =mg / kg Detection Limit = PCP, TeCP : 0.05 ppm (lower limit) or 0.5 ppm ; OPP : 0.5 ppm
< = Less Than ND = Not Detected
Remark : PCP Content Requirement in Annex XVII Item 22 of the Reach Regulation (EC) No : 1907/2006

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Test Method	Results	Requirements

Polycyclic Aromatic Hydrocarbons (PAHs) Analysis

INTERTEK IHTM AL.2.032 based on AfPS GS 2014:01

Blue interlining	Result	Requirement
BENZO(A)PYRENE	Not Detected	1 ppm
BENZO(E)PYRENE	Not Detected	1 ppm
BENZ(A)ANTHRACENE	Not Detected	1 ppm
BENZO(B)FLUORANTHENE	Not Detected	1 ppm
BENZO(J)FLUORANTHENE	Not Detected	1 ppm
BENZO(K)FLUORANTHENE	Not Detected	1 ppm
CHRYSENE	Not Detected	1 ppm
DIBENZO(A,H)ANTHRACENE	Not Detected	1 ppm

ppm (part per million) =mg / kg
Detection Limit = 0.1 ppm

Total Lead in Non Metal Products

CPSC-CH-E1002-08.3 Method followed by ICP-OES

White velcro	Not Detected	100 ppm (0.01%)

ppm (part per million) = mg / kg
< = Less Than
Detection Limit = 20 ppm

END OF TEST REPORT

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TEST REPORT

EN ISO 22612:2005
Resistance to Dry Microbial Penetration
(Annex A.2.6)

Client:

Address:

Sample: Sample 1: Dark Blue overall
Sample 2: Light Blue overall

Sample received on: May 08, 2020

Report Number: NPT/20050812689

Elaborated by: Ashley Madison

Place and date of issue: Sheridan, WY May 12, 2020

Dr. Joseph Andrew, Ph.D.
Head of Testing Laboratory

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

NATIONAL PROTECTIVE TESTING LLC

Test Standard: ISO/DIS 22612:2005
Name of tests: Resistance to Dry Microbial Penetration
Reference no: PBP-001

Test Purpose:
This test method is designed to determine resistance to dry microbial penetration
Sampling method:
Ten samples material tested. Sample size: 200x200mm

Testing methods used:
Test time: 30 minutes, Spores of Bacillus subtilis, ATCC 9372, Culture medium: TGE agar

Test conditions:
Min. 24hr, temperature of (20 ± 2) °C and a relative humidity of air of (65 ± 5) %.

Test Equipment:
Vibrating apparatus

Test Procedure:
To measure the barrier against contaminated dust, the test materials is pre- sterilised and then fixed into the test apparatus and dosed with contaminated (Bacillus Subtilis) talcum powder. An agar culture plate is located underneath.

The test apparatus is agitated or shaken. The particles which penetrate the material are cultured and counted after incubation of the agar plate and a non-contaminated test specimen is run as a control. The results (mean values from 10 single results at a given time) are measured in penetration log units

Test results:
The test results obtained are given in the tables as follows

No. of Sample	Unit	Result
1.sample	CFU	50,0
2.sample	CFU	80,0
3.sample	CFU	90,0
4.sample	CFU	60,0
5.sample	CFU	95,0
6.sample	CFU	65,0
7.sample	CFU	85,0
8.sample	CFU	45,0
9.sample	CFU	55,0
10.sample	CFU	30,0
Average	CFU	65,5
No. of Sample	**Unit**	**Result**
1.sample	Log10 CFU	1,7
2.sample	Log10 CFU	1,9
3.sample	Log10 CFU	2,0
4.sample	Log10 CFU	1,8
5.sample	Log10 CFU	2,0
6.sample	Log10 CFU	1,8
7.sample	Log10 CFU	1,9
8.sample	Log10 CFU	1,7
9.sample	Log10 CFU	1,7
10.sample	Log10 CFU	1,5
Average	Log10 CFU	1,8

	Requirement	Value	Result
Max	log10 CFU ≤ 2	1,80	Passed

Test conditions: challenge concentration 108 CFU/g talc. and 30 minutes vibration time.
For the purpose of this standard, log10 CFU ≤ 2 means maximum 300 CFU

Note: The results given in this Test Report apply only to the sample tested by our laboratory!
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Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
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EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

EKOTEKS

20014347-ing-Add

TEST REPORT
DENEY RAPORU

05-20

Gan163-203

Customer name:	UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.
Address:	15 Temmuz Mah. Gülbahar Cad. No:96 Bağcılar/İSTANBUL
Buyer name:	
Contact Person:	
Order No:	-
Article No:	-
Name and identity of test item:	Sample 1: Dark blue overall. Sample 2: Light blue overall.
The date of receipt of test item:	06.05.2020
Re-submitted/re-confirmation date:	-
Date of test:	06.05.2020-13.05.2020
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	Not specified.
Number of pages of the report:	9

Seal	***Date***	***Head of Testing Laboratory***
	13.05.2020	Sevim A. RAZAK 13.05.2020

Gan163-203

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

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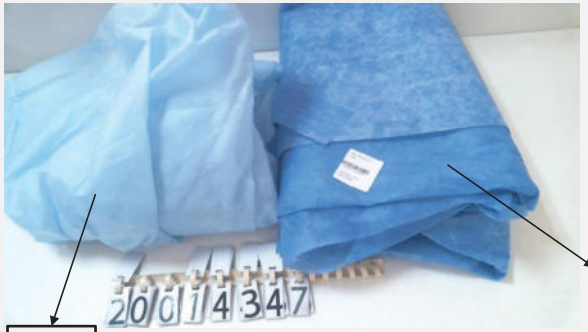
REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST/Sample 1&2		
Microbial Cleanliness (Bioburden) (1)	P	
Wet-Bacterial Penetration(1)	P	
PHYSICAL PROPERTIES TESTS /Sample 1&2		
Tensile Stregth / **Dry**	P	
Tensile Stregth / **Wet**	P	
Bursting Strength / **Dry**	P	
Bursting Strength / **Wet**	P	
P: Pass F: Fail R: Refer to retailer technologist. (1) This report was reissued to add this test result. Test results were evaluated according to EN 13795-1:2016 Standard Performance Properties Critical Sample Group limit values (Table 1)		

REMARK: Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified.If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2, providing a level of confidence of approximately 95 %. Tests marked (*) in this report are not included in the accreditation schedule.



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Testing reports without signature and seal are not valid.

TEST RESULTS

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: Ref: EN ISO 11737-1:2018 (*)

The sample is put in extraciton liquid after shaking well, inoculated on the agar.
After incubation at 30 ± 1 °C for 72 hours, growth microorganisms are counted on the agar.

Sample 1		
	RESULTS	**REQUIREMENT**
Microbial cleanliness (cfu/g)	170 cfu/100 cm^2	≤300 cfu/100 cm^2

***cfu= Colony forming unit.**

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: Ref: EN ISO 11737-1:2018 (*)

The sample is put in extraciton liquid after shaking well, inoculated on the agar.
After incubation at 30 ± 1 °C for 72 hours, gr owth microorganisms are counted on the agar.

Sample 2		
	RESULTS	**REQUIREMENT**
Microbial cleanliness (cfu/g)	150 cfu/100 cm^2	≤300 cfu/100 cm^2

***cfu= Colony forming unit.**

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EKOTEKS LABORATUVAR veGÖZETİM
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TEST RESULTS

Sample 1

Test Method: BS EN 22610: 2006 (Surgical drapes, garments and fresh air clothes used as medical devices for patients, hospital staff and equipment - Test method for determination of resistance to wet bacterial permeability) (*)

A test sample is placed on the agar plate on a rotating disc. Bacteria carrier material and coating film are placed on the test sample and all parts are fixed on the disk. A finger is placed on the test sample to apply a certain force (3N ± 0.02). The finger moves on the test sample over the entire surface of the agar within 15 minutes. 5 studies are carried out for 15 minutes. 6. The study is repeated by inverting the sample.

Sample amount:	5 pieces 25x25cm2
Carrier Material:	30 µm thin, 25x25cm2 Polyurethane Film
Coating Material:	25x25cm2 HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / ml):	1-4x104 kob / ml
Incubation Conditions:	(36 ± 1) °C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		Penetration Rate	
X1	100	RCUM1	0,1
X2	0	RCUM2	0,1
X3	200	RCUM3	0,4
X4	0	RCUM4	0,4
X5	150	RCUM5	0,6
Z	260		
T	710		

X1 ... ... X5: Number of colonies growing in 5 parallel petri in the same sample
Z: number of colonies growing in the sixth petri dish
T: X1 + X2 + X3 + X4 + X5 + Z

RCUM1 = X1/T
RCUM2 = (X2 + X1)/T
RCUM3 = (X3 + X2 + X1)/T
RCUM4 = (X4 + X3 + X2 + X1)/T
RCUM5 = (X5 + X4 + X3 + X2 + X1)/T

BARRIER INDEX (IB)		
	Result	Expected value (*)
IB	4,4	≥2,8

IB = 6 - (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)

* EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.

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TEST RESULTS

Sample 2

Test Method: BS EN 22610: 2006 (Surgical drapes, garments and fresh air clothes used as medical devices for patients, hospital staff and equipment - Test method for determination of resistance to wet bacterial permeability) (*)

A test sample is placed on the agar plate on a rotating disc. Bacteria carrier material and coating film are placed on the test sample and all parts are fixed on the disk. A finger is placed on the test sample to apply a certain force (3N ± 0.02). The finger moves on the test sample over the entire surface of the agar within 15 minutes. 5 studies are carried out for 15 minutes. 6. The study is repeated by inverting the sample.

Sample amount:	5 pieces 25x25cm2
Carrier Material:	30 µm thin, 25x25cm2 Polyurethane Film
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Microorganism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / ml):	1-4x104 kob / ml
Incubation Conditions:	(36 ± 1) °C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		Penetration Rate	
X1	100	RCUM1	0,1
X2	0	RCUM2	0,1
X3	200	RCUM3	0,3
X4	250	RCUM4	0,5
X5	300	RCUM5	0,7
Z	290		
T	1140		

X1 ... ... X5: Number of colonies growing in 5 parallel petri in the same sample
Z: number of colonies growing in the sixth petri dish
T: X1 + X2 + X3 + X4 + X5 + Z

RCUM1 = X1/T
RCUM2 = (X2 + X1)/T
RCUM3 = (X3 + X2 + X1)/T
RCUM4 = (X4 + X3 + X2 + X1)/T
RCUM5 = (X5 + X4 + X3 + X2 + X1)/T

BARRIER INDEX (IB)

	Result	Expected value (*)
IB	4,3	≥2,8

IB = 6 - (CUM1 + CUM2 + CUM3 + CUM4 +CUM5)

* EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.

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05-20

TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL CLOTHING AND DROPES -REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DROPES (*);

TENSILE STRENGTH; EN 29073-3:1996 (*)
Instron 5969 (Load: 50 kN), Strip Method.
Speed: 100 mm/min±10,Gauge length 200 mm.
Pre-load was not applied. Without wetting samples.
The average results are given for weft and warp direction of five samples
Performed in the conditioned room (20±2°C-65%±4).
Dry ;

Sample 1	**RESULT**	**REQUIREMENT**
Weft	44.0 N	☒ 20N (Dry)
Warp	46.0 N	☒ 20N (Dry)

TENSILE STRENGTH; EN 29073-3:1996 (*)
Instron 5969 (Load: 50 kN), Strip Method.
Speed: 100 mm/min±10,Gauge length 200 mm.
Pre-load was not applied. With wetting samples.
The average results are given for weft and warp direction of five samples
Performed in the conditioned room (20±2°C-65%±4).
Wet ;

Sample 1	**RESULT**	**REQUIREMENT**
Weft	41.3 N	☒ 20N(Wet)
Warp	48.8 N	☒ 20N(Wet)

BURSTING STRENGTH;; ISO 13938-1:1999
SDL ATLAS M229 tester. Test area: 30.5 mm diameter
Rate of increase in volume; 29 cm^3/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	**REQUIREMENT**
Dry ;	135.1 kPa	☒ 40 kPa (Dry)
Height at Burst*	7.9 mm	

Gen1163-2103

TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL CLOTHING AND DROPES -REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DROPES (*);

BURSTING STRENGTH;; ISO 13938-1:1999
SDL ATLAS M229 tester. Test area: 30.5 mm diameter
Rate of increase in volume; 45.2 cm^3/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).
Sample 1

	RESULT	REQUIREMENT
Wet ;	143.3 kPa	☒ 40 kPa (Wet)
Height at Burst*	8.4 mm	

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TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL CLOTHING AND DROPES -REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DROPES (*);

TENSILE STRENGTH; EN 29073-3:1996 (*)
Instron 5969 (Load: 50 kN), Strip Method.
Speed: 100 mm/min±10,Gauge length 200 mm.
Pre-load was not applied. Without wetting samples.
The average results are given for weft and warp direction of five samples
Performed in the conditioned room (20±2°C-65%±4).
Dry ;

	RESULT	REQUIREMENT
Sample 2		
Weft	79.4N	☒ 20N (Dry)
Warp	78.2N	☒ 20N (Dry)

TENSILE STRENGTH; EN 29073-3:1996 (*)
Instron 5969 (Load: 50 kN), Strip Method.
Speed: 100 mm/min±10,Gauge length 200 mm.
Pre-load was not applied. With wetting samples.
The average results are given for weft and warp direction of five samples
Performed in the conditioned room (20±2°C-65%±4).
Wet ;

	RESULT	REQUIREMENT
Sample 2		
Weft	85.6 N	☒ 20N (Wet)
Warp	87.0 N	☒ 20N (Wet)

BURSTING STRENGTH;; ISO 13938-1:1999
SDL ATLAS M229 tester. Test area: 30.5 mm diameter
Rate of increase in volume; 29 cm^3/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).
Sample 2

	RESULT	REQUIREMENT
Dry ;	136.7 kPa	☒ 40 kPa (Dry)
Height at Burst*	14.2mm	

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20014347-ing-Add
05-20

TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL CLOTHING AND DROPES -REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DROPES (*);

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
Rate of increase in volume; 45.2 cm^3/min.
The average results are given of five samples.
Performed in the conditioned room (20±2˚C-65%±4).
Sample 2

	RESULT	REQUIREMENT
Wet ;	170.3 kPa	☒ 40 kPa (Wet)
Height at Burst*	21.9 mm	