







PROTECTIVE COVERALL

At PROTEX we are very serious about protection. A uniquely sewn pattern that reduces the number of seams on body top by almost 40% against a conventional designs, the use of thoroughly tested Water Proof material and options for Disposable and Reusable material, we provide the right protection for your every levels of in-filed risk profile. All our Hazmat Suit are made in accordance to AAMI PB70:2012 guideline.

*some test results pending 3rd party verification

SIZE CHART

M (+/- 165 CM)

L (+/- 175 CM)

XL (+/- 185 CM)

Protective Coverall is made with materials in accordance with

ANSI/AAMI PB70:2012

FK.01.02/VI/526-e/2020

AKD 216 030 20 575





INTEGRATED HOOD

Integrated hood design for contamination safety during donning of suit

SUIT TESTED

simulated workplace functional testing, based on doctor recomendation and approval

NECK ENCLOSURE

zipper move up to the upper neck area for maximum protection

OVERALL DESIGN

fabric diagonal cut to minimize number of seams and joint

ZIPPER COVER

zipper flap to secure zipper area

ELASTIC CUFF

elastic cuff on arm and leg area to ensure perfect fit for every user size

SPECIAL PATTERN

A unique pattern allowing freedom of movement on elbow and knees

SHOE COVER

Elastic shoe cover equipped with simple tie in, for easy donning and doffing

PROTEX D / DS



Levels of Barrier Protection - AAMI PB70:20121

Choose the right gown by matching the color on the neck binding to the AAMI level on the chart.

	♦LEVEL1	66LEVEL2		666 LEVEL 3	
Test	AATCC 42:2000	AATCC 42:2000	AATCC 127:1998	AATCC 42:2000	AATCC 127:1998
Requirements at 4% AQL	Water impact ≤ 4.5 g	Spray impact ≤ 1.0 g	Hydrostatic Pressure ≥ 20 cm	Spray Impact ≤ 1.0 g	Hydrostatic pressure ≥ 50 cm
Anticipated Risk of Exposure	Low	Moderate		Modera	ate to High



BADAN PENELITIAN DAN PENGEMBANGAN INDUSTRI

LABORATORIUM PENGUJIAN

BALAI BESAR TEKSTIL

Jalan Jenderal A. Yani No. 390 Bandung 40272 Telepon (022) 7206214, 7206215 Fax (022) 7271288 E-mail: texirdti@bdg.centrin.net.id

ASLI LAPORAN UJI

No. 674b/EV/IV/2020

Hal. 1/1

No. 2365/BPPI/BBT/PNP/04/2020

Type: WI/Dw

WO. No.

674/EV/IV/2020

Contoh

1 (satu) contoh kain tenun

Dengan

Surat

Kondisi

Normal

Nomor

Tanggal

Diterima tgl.

13 April 2020

No.

Jenis Uji

Hasil Uji

Cara Uii

Tanda contoh

Satin

Contoh diserahkan oleh pelanggan

1.

Impact Penetration, g

0.0

AATCC TM 42-2017

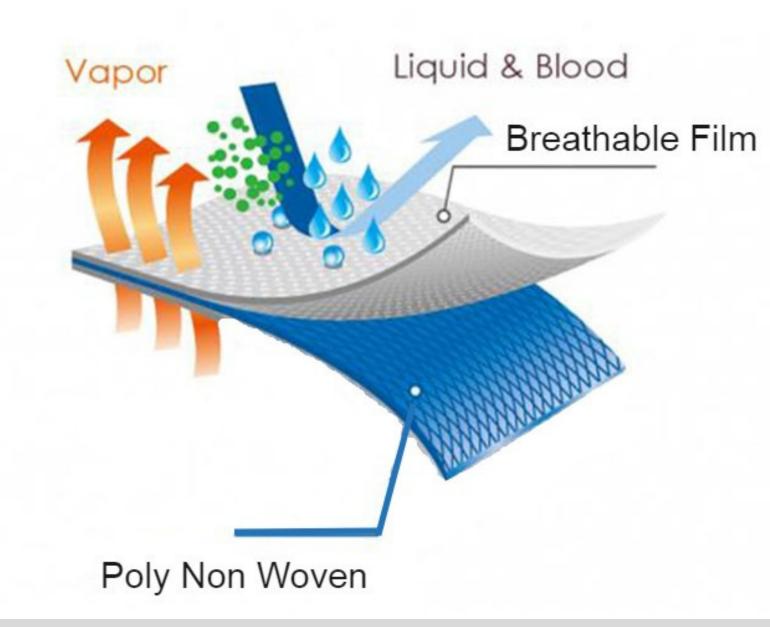
CONTOH

Bandung, 15 April 2020

BALAI BESAR TEKSTIL LABORATORIUM PENGUJIAN TEKSTIL Signatoris,

Tembusan: Arsip

NDRA/KURNIAWAN



Non Woven combined with Polyethelne Membrane our material for protective coveralls with durable materials and design features that are ready for harsh environments, material is made with a non-porous material that is suitable for certain asbestos removal, pesticide spraying, pharmaceutical processing, and aerosol producing medical procedure. (PROTEX D PROTEX DS)



TEST REPORT

NUMBER : JKTT20013028 : 02-Sep-2020 DATE

APPLICANT : PT SIPATAMODA INDONESIA

JL RAYA BATUJAJAR KM 3.2, CIMAHI, BANDUNG,

40561, INDONESIA

: SOFIAN ATTN

: ONE (1) PIECE OF SUBMITTED POLYETHYLENE SAMPLE DESCRIPTION

BREATHABLE FILM NON WOVEN COMPOSITE FABRIC SAMPLE

DATE RECEIVED/DATE TEST STARTED : 27 Aug 2020

FIBER CONTENT : -ORDER NO. : -STYLE NO.

TEST CONDUCTED : AS PER THE REQUEST OF THE APPLICANT. FOR FURTHER DETAILS PLEASE REFER TO ENCLOSED PAGE(S)

CONCLUSION :

WATER RESISTANCE BY HYDROSTATIC PRESSURE

M = MEETS THE SUBMITTED REQUIREMENT

F = FAILS TO MEET THE SUBMITTED REQUIREMENT

= NO COMMENT DUE TO NO REQUIREMENT PROVIDED S = SATISFACTORY

M1 = CONFORMS TO THE PROVIDED CARE INSTRUCTION U* = UNSATISFACTORY

M* = CONFORMS TO THE DECLARED FIBER CONTENT

1 * = PLEASE REFER TO BELOW COMMENT

F# = FAILS TO MEET BUYER'S REQUIREMENT

A = COMMERCIALLY ACCEPTABLE

U = COMMERCIALLY UNACCEPTABLE

* = NO SUBMITTED INFORMATION

D = DATA

M# = MEETS BUYER'S

REQUIREMENT

F* = DOES NOT CONFORM TO THE DECLARED FIBER CONTENT

F1 = DOES NOT CONFORM TO THE PROVIDED CARE INSTRUCTION

CA = CONDITIONAL APPROVE C = CONFORM LABEL

N/A = NOT APPLICABLE

Authorized By

FOR INTERTEK INDONESIA [JAKARTA]

The same NOVITA PURBA

TEXTILE LABORATORY MANAGER

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TEST REPORT

NUMBER: JKTT20013028 DATE : 02-Sep-2020

TEST CONDUCTED (AS REQUESTED BY THE APPLICANT)

1. WATER RESISTANCE BY HYDROSTATIC PRESSURE

(AATCC 127-2018,

TESTED ON COATED SIDE

			Requirement
RESULT	(1)	241	
		CMH ₃ O	
	(2)	245	
		CMH ₂ O	
	(3)	253	
		CMH ₂ O	
AVERAGE		246	LEVEL 3 :
		CMN C	≥ 50 CMH ₂ O

REMARK:

≥ = MORE THAN

CMH2O = CENTIMETER OF WATER

END OF THE TEST REPORT

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ISO 16604 Viral Penetration Final Report

Test Article: C100

Study Number: 1294475-S01 Study Received Date: 30 Apr 2020

Testing Facility: Nelson Laboratories, LLC

6280 S. Redwood Rd.

Salt Lake City, UT 84123 U.S.A.

Test Procedure(s): Standard Test Protocol (STP) Number: STP0174 Rev 04

Deviation(s): None

Summary: This test method was performed to evaluate the barrier performance of protective materials which are intended to protect against blood borne pathogen hazards. Test articles were conditioned for a minimum of 24 hours at 21 ± 5°C and 60 ± 10% relative humidity (RH), and then tested for viral penetration using a ΦX174 bacteriophage suspension. At the conclusion of the test, the observed side of the test article was rinsed with a sterile medium and assayed for the presence of ΦX174 bacteriophage. The viral penetration method complies with ISO 16604. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested: 3 Number of Test Articles Passed: 3

Test Article Side Tested: Film Side

Test Article Preparation: Cut from the Material at Random

Test Article Sealed: Paraffin Wax

Exposure Procedure: C (no retaining screen; 1.75 kPa)

Compatibility Ratio: 1.0, per sponsor Settle Plate Results: Acceptable

Results:

Study Director

Test Article Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
1-3	2.1 x 10 ⁸	2.1 x 10 ⁸	<18	None Seen	Pass
Negative Control	2.1 x 10 ⁸	2.1 x 10 ⁸	<1ª	None Seen	Acceptable
Positive Control	2.1 x 10 ⁸	2.1 x 10 ⁸	TNTCD	Yes	Acceptable

A value of <1 plaque forming units (PFU)/mL is reported for assay plates showing no plaques.

TNTC = PFU were too numerous to count.





Jennifer Jorgenson electronically approved

Jennifer Jorgenson

15 May 2020 20:41 (+00:00) Study Completion Date and Time

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com is FRT0174-0001 Rw 5

Water Resistance: Hydrostatic Pressure Final Report

Test Article: C100

Purchase Order: 200.011.PU8.D.20 Study Number: 1285362-S01 Study Received Date: 07 Apr 2020

Testing Facility: Nelson Laboratories, LLC

6280 S. Redwood Rd.

Salt Lake City, UT 84123 U.S.A.

Test Procedure(s): Standard Test Protocol (STP) Number: STP0071 Rev 11

Deviation(s): None

Summary: This test method was performed to evaluate the resistance of a material to the penetration of water under hydrostatic pressure using apparatus option 2: Hydrostatic Head Tester. The hydrostatic pressure test method complies with AATCC Test Method 127:2017 and ANSI/AAMI PB70:2012, sampling was at the discretion of the sponsor. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Article Preparation: Received Pre-Cut

Test Article Size: Minimum of 200 x 200 mm (~8 x 8 in.)

Test Article Side Tested: Film Side

Laboratory Conditions: 22°C and 29% relative humidity (RH)

Rate of Increase: 60 mbar/minute

Results:

Sept. 1745	Test Article Number	Failure Pressure (cm H ₂ O)
	1	266
	2	264
	3	245

Test Method Acceptance Criteria: Testing was performed using a rate of increase (pressure gradient) of either 10 mbar per minute, 60 mbar per minute, and/or other pressure gradients requested by the sponsor.



Jennifer Jorgenson, B.S., RM(NRCM)

TESTAL ABOVE



801-290-7500

nelsonlabs.com

sales@nelsonlabs.com

hmm

Page 1 of 2

Water Resistance: Impact Penetration Final Report

Test Article: C100

Purchase Order: 200.011.PU8.D.20 Study Number: 1285364-S01

Study Received Date: 07 Apr 2020
Testing Facility: Nelson Laboratories, LLC

6280 S. Redwood Rd.

Salt Lake City, UT 84123 U.S.A.

Test Procedure(s): Standard Test Protocol (STP) Number: STP0072 Rev 12

Deviation(s): None

Summary: This test method was performed to evaluate the resistance of a material to the penetration of water by impact using the Type I Tester apparatus. The impact penetration test method complies with AATCC Test Method 42 and is in accordance with ANSI/AAMI PB70. Sampling was at the discretion of the sponsor. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Article Preparation: Received Pre-Cut

Test Article Size: ~178 x 330 mm (7 x 13 in)

Test Article Side Tested: Film Side

Blotter Paper: Grade 989 (Lot #112645/003)

Blotter Paper Size: 150 x 225 mm Average Flow Rate: 22 sec

Results:

Study Director

801-290-7500

Test Article Number	Visual Renetration	Amount of Penetration (g)
1	None Seen	<0.1
2	None Seen	<0.1
3	None Seen	<0.1

Average Amount of Penetration: <0.1 g

Jennifer Jorgenson, B.S., RM(NRCM)

Study Completion Date

1285364-S01 nelsonlabs.com | sales

sales@nelsonlabs.com

hmm

Page 1 of 1



BADAN PENELITIAN DAN PENGEMBANGAN INDUSTRI

LABORATORIUM PENGUJIAN BALAI BESAR TEKSTIL

Jalan Jenderal A. Yani No. 390 Bandung 40272 Telepon (022) 7206214, 7206215 Fax (022) 7271298. E-mail: taxintli@bdg.centrin.net.id



Type: WI/Dw

ASLI LAPORAN UJI

No. 10335/EV/VI/2020

Halt 171

WO. No.

1033/EV/VE/2020

Dengan Lisan Nemor

04 Juni 2020 Tanggal

No : 3662/BPPVBBT/PNP/D6/2020

I (satu) contoh kain nir tenun Contok

Normal. Koadai 04 Juni 2020 Diterima tgl.

Nico.

Jenis Uni

Hazil Uji

Cara, Uri.

Tanda contah

Medifub Soul

Costoh diserahkan oleh pelanggan

Days tahan air:

- Uji tekaran hidrostatik, em

362,0

AATCC TM 127-2014

Opsi 2

CONTOH

Bandang, 10 Juni 2020

BALAI BESAR TEKSTIL LABORATORIUM PENGUJIAN TEKSTIL

Signatoria,

MORA KURNIAWAN

Tembusin: Acsip



Hat. 3/1

BADAN PENELITIAN DAN PENGEMBANDAN INDUSTRI

LABORATORIUM PENGUJIAN BALAI BESAR TEKSTIL

Jalan Jenderal A, Yani No. 350 Bandung 40272 Telepon (022) 7206214, 7206215 Fax (022) 7271268 E-mail: toxindli@bdg.centrin.net.ld

ASLI LAPORAN UJI

No. 10337/EV/VE/2020

1 (satu) contoh kain nir terran Contoh 1 1033/EV/VV2920 WO. No. Dengari Lisan. Normal Kondoi Nomer 04 Juni 2020 Medifab Scalandhargy

Medifab Scalandhargy

Sermon From Personal

Personal trattal

Control Diterizea tgd. : 04 Juni 2020 Tanggal Bertalett tertuk contan yang aran Laboratorium Period anggan

0,0 Bally E Cars Up No.

No: 3003/BPP/BBT/PNP/06/2020

AATCC TM 42-2017 Impact Penetration, g. L

Bandeng, 10 Juni 2020

Type: WhDw

BALAI BESAR TEKSTIL LABORATORIUM PENGUJIAN TEKSTIL Signatoris,

MA KURNIAWAN

Tembusaa: Atsip



KEMENTERIAN KESEHATAN REPUBLIK INDONESIA DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN

Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950 Telepon : (021) 5201590 Pesawat 2029, 8011 Faksimile : (021) 52964838 Kotak Pos : 203



Berdasarkan Peraturan Menteri Kesehatan R.I Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

NOMOR IZIN FOAR

ALAT KESEHATAN

KEMENKES RI AKD 21603020575

Nama Dagang / Merek : PROTEX Hazmat Suit Coverall

Kelompok / Kelas Resiko : Non Elektromedik Non Steril / B

Kategori Produk : Peralatan Bedah Umum dan Bedah Plastik

Sub Kategori : Peralatan Bedah

Jenis Produk : Surgical apparel.

Tipe / Ukuran : M, L, XL

Kemasan : Plastik

Nama Produsen / Pabrikan : PT. SIPATA MODA INDONESIA, Jawa Barat

Nama Pendaftar : PT. SIPATA MODA INDONESIA, Jawa Barat

Atas dasar lisensi dari : -

Ketentuan

- Persetujuan izin edar berlaku sampai dengan 02 April 2025.
- Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
- Produsen hanya boleh menyalurkan produknya melalui Penyalur Alat Kesehatan (PAK).
- Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
- Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
- Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.



KEMENTERIAN KESEHATAN REPUBLIK INDONESIA DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN

Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950 Telepon : (021) 5201590 Pesawat 2029, 8011 Faksimile : (021) 52964838 Kotak Pos : 203



KEPUTUSAN DIREKTUR JENDERAL KEFARMASIAN DAN ALAT KESEHATAN KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

NOMOR: FK.01.01/VI/3544-e/2020

TENTANG SERTIFIKAT DISTRIBUSI ALAT KESEHATAN

DIREKTUR JENDERAL KEFARMASIAN DAN ALAT KESEHATAN KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

MEMBACA

- Surat Permohonan PT. SIPATA MODA INDONESIA, Jawa Barat Nomor 07/FA/SM/IX/20 tanggal 5 September 2020 tentang Permohonan Sertifikat Distribusi Alat Kesehatan dengan kelengkapan persyaratan tertanggal 8 September 2020.
 - Hasil analisa terhadap Permohonan Sertifikat Distribusi Alat Kesehatan PT. SIPATA MODA INDONESIA.

MENIMBANG

: bahwa permohonan PT. SIPATA MODA INDONESIA, Jawa Barat tersebut telah memenuhi persyaratan dan dapat disetujui, oleh karena itu dianggap perlu menerbitkan Sertifikat Distribusi Alat Kesehatan untuk yang bersangkutan.

MENGINGAT

- 1. Peraturan Menteri Kesehatan Nomor 1191/MENKES/PER/VIII/2010 tentang Penyaluran Alat Kesehatan.
 - Peraturan Menteri Kesehatan Nomor 26 Tahun 2018 tentang Pelayanan Perizinan Berusaha Terintegrasi Secara Elektronik Sektor Kesehatan.

MEMUTUSKAN:

MENETAPKAN

Kesatu

Memberikan Sertifikat Distribusi Alat Kesehatan kepada:

Nama Perusahaan : PT. SIPATA MODA INDONESIA

Nomor Induk Berusaha : 8120102971539

NPWP : 21.056.031.4-421.000

Alamat Perusahaan : Jl. Raya Batujajar KM 3,2 Kel. Giriasih,

Kec. Batujajar, Kab. Bandung Barat,

Jawa Barat

Telp. 022-6866178

Nama Direktur / Pimpinan : IAN SYARIF

Nama Penanggung Jawab Teknis : IWAN SETIAJI

(D.III-Teknik Kimia)

Alamat Gudang : Jl. Raya Batujajar KM 3,2 Kel. Giriasih,

Kec. Batujajar, Kab. Bandung Barat,

Jawa Barat

Alamat Bengkel / Workshop : -

Kedua

Jenis alat kesehatan yang didistribusikan sebagaimana yang tercantum dalam Lampiran yang merupakan bagian tidak terpisahkan dari Keputusan Direktur Jenderal ini.



Catatan:

- UU ITE No 11 Tahun 2008 Pasal 5 ayat 1
 "Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah."
- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSrE



Certificate of Registration

This is certify that the Medical Devices Quality Management System of:

PT. SIPATA MODA INDONESIA

Jalan Raya Batujajar KM 3,2, Batujajar, Giriasih, Kab.Bandung Barat, INDONESIA

has been independently assessed and is complying with the requirements of :

ISO 13485:2016

This certificate is applicable to the following product or service ranges:

Manufacture of Textiles and Including Trade

1st Surveillance on or before : July, 28th, 2021 2nd Surveillance on or before : July, 28th, 2022 Recertification on or before : Aug, 27th, 2023 Certificate No : 200828001081MDK001

Date of Expiry : Aug, 27th, 2023



VRC International is the brand of PT. Valuabilitas Reabilitas Certi on conformity assessment services.

VRC International has strictly followed all requirement of ISO 17021 for Conformity Assessment body and met all requirements of all Mandatory Documents of International Accreditation Forum for the Management System Certification Scheme

The approval is subject to the company maintaining is system the required standard standard for the management system certification scheme

The approval is subject to the company maintaining is system the required standards, which will be monitored by VRC International. The above audited accredited scope shall be monitored by VRC International Management scheme regulation.

VRC International is a Conformity Assessment Body as per requirement of ISO 17021 and meet the requirement of all Mandatory Documents of International Accreditation Forum for the Management System Certification Scheme, in the issuance of this certificate, VRC International, assumes no liability to any party other than to the Client and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with VRC's requirements for systems certification.

The certificate remains the property of VRC International, to whom it must be returned upon request

PROSES PRODUKSI APD





Factory Infra-Structure - Cutting

















Fabrics Machine Inspection





Name of Machine	Merk	Qua	ntity
Single Needle Machine	Brother	56	Unit
Single Needle Machine	Typical	112	Unit
Single Needle Machine	Siruba	9	Unit
Single Needle Machine	Juki	10	Unit
Single Needle Machine	Brother	31	Unit
Single Needle Machine	Typical	17	Unit
Single Needle Machine	Unicorn	1	Unit
Single Needle Machine	Juki	1	Unit
Single Needle Machine	Sunstar	14	Unit
Double Needle Machine	Brother	13	Unit
Double Needle Machine	Brother	17	Unit
Double Needle Machine	Nitaka	1	Unit
Double Needle Machine -			
Chainstitch	Mitsubishi	9	Unit
Single Needle Machine - Chainstitch	Singer	1	Unit

Overlock Machine	Typical	123	Unit
Overlock Machine	Yamato	49	Unit
Overlock Machine	Siruba	10	Unit
Overlock Machine	Juki	20	Unit
Overlock Machine	Typical	20	Unit
Overlock Machine	Yamato	5	Unit
Overlock Machine	Juki	4	Unit
Overdeck Machine	Brother	1	Unit
Overdeck Machine	Yamato	1	Unit
Overdeck Machine	Kingtex	12	Unit
Overdeck Machine	Kingtex	47	Unit
Overdeck Machine	Siruba	40	Unit
Overdeck Machine	Typical	59	Unit
Bartacking Machine	Brother	11	Unit
Button Attaching Machine	Brother	1	Unit

Button Attaching Machine	Typical	1	Unit
Button Holing Machine	Juki	1	Unit
Button Holing Machine	Typical	10	Unit
Kansai Machine (for Piping)	Siruba	20	Unit
Kansai Machine (for Piping)	Spesial	2	Unit
Dramp Kansai Machine		6	Unit
Test Snap Machine	Saf-Q	1	Unit
Snap Machine		13	Unit
Iron Steam	Silver Star/Segye	32	Unit
Vacuum Table	TGP	37	Unit
Label Cutting Machine		2	Unit
Roll Thread Machine		2	Unit
Fabric Cutting Machine	KM/Eastman	6	Unit
Fabric Cutting Machine	Sulee	8	Unit
Cutting Table 17 x 2 Mtr		3	Unit

Fabric Inspection Machine	Mogochi	1	Unit
Scale	Gewinn	1	Unit
Band Knife Machine	Tax	1	Unit
Cutting Acrylic Machine	Total Attachments	1	Unit
Press Machine (Heat Seal Transfer)	Yi Zi Shun	9	Unit
Marker Machine	Superwinda	1	Unit
Piping Cutting Machine	Saloon	1	Unit
Rolling Machine	Saloon	1	Unit
Hand Metal Detector Machine	Besta	1	Unit
Metal Detector Machine	Besta	1	Unit
Conveyor		1	Unit
Vacuum Cleaner		1	Unit
Compresor Machine		4	Unit
Generator	Mitsubishi	1	Unit
Boiler Machine	Miura	1	Unit
Total of Machine	s	865	Unit