# Test Report

*Issued to*

**MDK (SHANGHAI) MEDICAL PACKING CO., LTD**
No. 233 Fengjian Road, Fengcheng Town,
Fengxian District,
Shanghai City,
China

*for*

**Single-use Protective Clothing**

*Acc. to*

**Standard(s)**

**ENISO13688:2013**
**EN14126:2003 (Type 6-B)**
**EN13034:2005+A1:2009 (Type 6)**

*Issued by*

**National Technical Certification**
**Nationaux de Certification Technique**
217 rue des reculetes
73123 Paris
France

# TEST REPORT

| Test Report No. NTC20033008.MDK.PPE | Rev.: 1.0 | Date 19/03/2020 |
|---|---|---|
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| | | |
|---|---|---|
| **Client:** | MDK (SHANGHAI) MEDICAL PACKING CO., LTD<br><br>No. 233 Fengjian Road, Fengcheng Town,<br>Fengxian District,<br>Shanghai City,<br>China | |
| **Test Item** | Single-use Protective Clothing | |
| **Identification / Type No.:** | MDK-PC002-S, MDK-PC002-M, MDK-PC002-L,<br>MDK-PC002-XL, MDK-PC002-XXL, MDK-PC002-XXXL. | |
| **Order Content** | CE Approval | |
| **Test Specification:** | EN ISO 13688:2013 – Protective clothing – General requirements<br>EN 14126:2003 – Protective clothing – Performance requirements and test methods for protective clothing against infective agents (Type 6-B)<br>EN 13034: 2005 + A1:2009 Protective clothing against chemicals - Chemical protective clothing offering limited protective performance against liquid chemicals (Type 6) | |
| **Date of Receipt** | 05.03.2020 | **Detailed photo documentation see Identification and Description of Samples to this report** |
| **Testing Period** | 06.03.2020 to 19.03.2020 | |
| **Test Result** | Pass | |

**Reviewed by:**

Name: A.Vallawhil
Position: Chief Manager
Date: 19.03.2020

**Condition of the test item at delivery:** Test item complete and undamaged

Legend: 1 = very good 2 = good 3 = satisfactory 4 = sufficient 5 = poor
P(ass) = passed a.m. test specifications(s)
F(ail) = failed a.m. test specifications(s)
N/A = not applicable
N/T = not tested

This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.

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# TEST REPORT



**Identification and Description of Samples:**

| | |
|---|---|
| Description: | Single-use Protective Clothing, Made of composite non-woven fabric, non-sterilized for single use. |
| Model(s): | MDK-PC002-S, MDK-PC002-M, MDK-PC002-L, MDK-PC002-XL, MDK-PC002-XXL, MDK-PC002-XXXL. |
| Basic Tested Model: | MDK-PC002-XL |
| Photo(s): |    |
| Remark: | All models have same construction and material except for model name and size. |

# TEST REPORT



**Part I - Tests Conducted Summary**

**Test standard: EN ISO 13688:2013 – Protective clothing – General requirements**

**EN 14126:2003 – Protective clothing - Performance requirements and tests methods for protective clothing against infective agents (Type 6-B)**

**EN 13034: 2005 + A1:2009 Protective clothing against chemicals - Chemical protective clothing offering limited protective performance against liquid chemicals (Type 6)**

Tests Carried Out :

| **Tests - EN ISO 13688:2013** | **Result** |
|---|---|
| 1. Azo Dyes | Pass |
| 2. pH Value | Pass |
| 3. Ergonomics | Pass |
| 4. Sizing | Pass |

| **Tests - EN 14126:2003 (Type 6-B)** | **Result** |
|---|---|
| 1. Mechanical and flammability requirements | Pass |
| 2. Chemical requirements | Pass |
| 3. Resistance to penetration by contaminated liquids under hydrostatic pressure | Pass |
| 4. Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids. | Pass |
| 5. Resistance to penetration by contaminated liquid aerosols | Pass |
| 6. Resistance to penetration by contaminated solid particles. | Pass |

| **Tests - EN 13034:2005+A1:2009 (Type 6)** | **Result** |
|---|---|
| 1. Protective clothing against chemicals | Pass |
| 2. Performance requirements for seams joins and assemblages | Pass |
| 3. Performance requirements for whole suit | Pass |

**Part II - Result Details:**

**II-1 Test standard: EN ISO 13688:2013 – Protective clothing – General requirements**

**1. Azo Dyes**

Test Method:
All Textile: According to EN ISO 14362-1:2017– Analysis was conducted with GC-MS/ HPLC-DAD.

| Amines | CAS No. | Result (mg/kg) | |
|---|---|---|---|
| | | Body | Zipper tape |
| 4-Aminobiphenyl | 92-67-1 | N/D | N/D |
| Benzidine | 92-87-5 | N/D | N/D |
| 4-Chlor-o-toluidine | 95-69-2 | N/D | N/D |
| 2-Naphthylamine | 91-59-8 | N/D | N/D |
| o-Aminoazotoluene | 97-56-3 | N/D | N/D |
| 5-nitro-o-toluidine / 2-Amino-4-nitrotoluene | 99-55-8 | N/D | N/D |
| 4-Chloroaniline | 106-47-8 | N/D | N/D |
| 4-methoxy-m-phenylenediamine / 2,4-Diaminoanisole | 615-05-4 | N/D | N/D |
| 4,4'-Diaminodiphenylmethane | 101-77-9 | N/D | N/D |
| 3,3'-Dichlorobenzidine | 91-94-1 | N/D | N/D |
| 3,3'-Dimethoxybenzidine | 119-90-4 | N/D | N/D |
| 3,3'-Dimethybenzidine | 119-93-7 | N/D | N/D |
| 4,4'-methylenedi-o-toluidine / 3,3'-Dimethyl-4,4'-diaminodiphenylmethane | 838-88-0 | N/D | N/D |
| p-Cresidine | 120-71-8 | N/D | N/D |
| 4,4'-Methylene-bis-(2-chloroaniline) | 101-14-4 | N/D | N/D |
| 4,4'-Oxydianiline | 101-80-4 | N/D | N/D |
| 4,4'-Thiodianiline | 139-65-1 | N/D | N/D |
| o-Toluidine | 95-53-4 | N/D | N/D |
| 4-methyl-m-phenylenediamine / 2,4-Toluylendiamine | 95-80-7 | N/D | N/D |
| 2,4,5-Trimethylaniline | 137-17-7 | N/D | N/D |
| 4-aminoazobenzene | 60-09-3 | N/D | N/D |
| O-Anisidine | 90-04-0 | N/D | N/D |
| **Conclusion** | | **Pass** | **Pass** |

Note: N/D = Not Detected(<MDL)
MDL(Method Detection Limit) = 5 mg/kg (for individual compound)
Max Limit: N/D

## 2. pH Value

Test Method: According to ISO 3071:2005; 0.1mol/l KCL extraction

| | All Textile | Requirement |
|---|---|---|
| pH value | 6.3 | >pH3,5 and < pH9,5 |
| Conclusion | -- | |

Note: pH value of extraction medium 6.0
Temperature of the extraction solution 22°C

## 3. Ergonomics

| | |
|---|---|
| Standard | EN ISO 13688:2013 |
| Reference | MDK-PC002-S, MDK-PC002-M, MDK-PC002-L, MDK-PC002-XL, MDK-PC002-XXL, MDK-PC002-XXXL |
| Result | The ergonomics verification has been performed by physical dimensions commensurate with the size found. According to the inspection of the garment, this fulfills ergonomics requirement. |

## 4. Sizing

| | |
|---|---|
| Standard | EN ISO 13688:2013 |
| Reference | MDK-PC002-S, MDK-PC002-M, MDK-PC002-L, MDK-PC002-XL, MDK-PC002-XXL, MDK-PC002-XXXL |
| Result | After checking the sizes, these are considered acceptable. |

## II-2 Test standard: EN 14126:2003 – Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

### 4.1 Materials requirements

#### 4.1.1 General

**Result**

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. — N/A

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. — N/A

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. — Pass

#### 4.1.2 Mechanical and flammability requirements

**Result**

The materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of EN 14325. — Pass (see table below)

| Classification | Class | Test Method | Remark |
|---|---|---|---|
| Abrasion resistance | 1 of 6 | EN ISO 12947-2 | > 10 rubs |
| Flex cracking resistance | 3 of 6 | EN 14325 | > 5000 cycles |
| Flex cracking resistance at -30°C | 4 of 6 | EN 14325 | > 1000 cycles |
| Trapezoidal tear resistance | 3 of 6 | EN ISO 9073-4 | > 40 N |
| Tensile strength | 2 of 6 | EN ISO 13934-1 | > 60 N |
| Puncture resistance | 1 of 6 | EN 863 | > 5 N |
| Resistance to flame | 5 of 6 | EN 13274-4 | stops for 5 s in the flame |
| Seam strength | 3 of 6 | EN ISO 13934-1 | > 75 N |

#### 4.1.3 Chemical requirements

**Result**

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 EN 14325. — Pass (see table below)

| Tests | Class | Test Method | Result |
|---|---|---|---|
| Permeation resistance by breakthrough time | 3 of 6 | ISO 6529, Method A | > 60 min |
| Permeation resistance by cumulative permeation time | 3 of 6 | ISO 6529 | > 60 min [1] |
| Repellency to liquids | 3 of 3 | EN ISO 6530 | > 90 % |
| Penetration to liquids | 3 of 3 | EN ISO 6530 | < 1 % |
| [1] Cumulative mass at 20 µg/cm$^2$. | | | |

### 4.1.4 Performance requirements against penetration by infective agents

#### 4.1.4.1 Resistance to penetration by contaminated liquids under hydrostatic pressure

**Result**
Pass
(Class 3)

When tested in accordance with ISO 16603 and ISO 16604 the material shall be classified according to the levels of performance given in Table 1, as obtained in the bacteriophage test (ISO 16604).

Table: Resistance to penetration by blood/fluids under pressure
(ISO 16603:2004)

| Hydrostatic pressure | Penetration | Pass |
|---|---|---|
| 3.5 kPa | NO | Class 3 of 6 |

Table: Resistance to penetration by blood borne pathogens
(ISO 16604:2004, Phi-X174 method)

| Hydrostatic pressure | Penetration | Pass |
|---|---|---|
| 3.5 kPa | NO | Class 3 of 6 |

#### 4.1.4.2 Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids

**Result**
Pass
(Class 6)

When tested in accordance with Annex A the material shall be classified according to the levels of performance given in Table 2.

Table: Resistance to wet bacterial penetration (mechanical contact)
(ISO 22610:2018)

| Breakthrough time, t min | Penetration | Pass |
|---|---|---|
| t >75 | NO | Class 6 of 6 |

#### 4.1.4.3 Resistance to penetration by contaminated liquid aerosols

**Result**
Pass
(Class 3)

When tested in accordance with ISO 22611 the material shall be classified according to the levels of performance given in Table 3.

Table: Resistance to biologically contaminated aerosols
(ISO 22611:2003)

| Penetration ratio (log) | Penetration | Pass |
|---|---|---|
| log >5 | NO | Class 3 of 3 |

**4.1.4.4 Resistance to penetration by contaminated solid particles** — **Result**

When tested in accordance with ISO 22612 the material shall be classified according to the levels of performance given in Table 4. — Pass (Class 3)

Table: Resistance to penetration by dry microbial contaminated powders (ISO 22612:2005)

| Penetration (log cfu) | Penetration | Pass |
|---|---|---|
| ≤ 1 | NO | Class 3 of 3 |

**4.2 Performance requirements for seams, joins and assemblages** — **Result**

Seams, joins and assemblages of protective clothing against infective agents shall fulfil the requirements specified in the relevant clauses of EN 14325 Seam strength shall be classified according to 5.5 of EN 14325. — Pass (Class 3)

| Clause of EN 14325 | | Test Method | Result | Class | Comment |
|---|---|---|---|---|---|
| 5.2 | Pre-conditioning (5 cycles of cleaning) | Not applicable Limited Use | -- | -- | -- |
| 5.5 | Seam Strength | EN ISO 13935-2 | Leg seam = 108.2N<br>Arm seam = 103.9N<br>Front seam = 121.6N<br>Rise seam = 117.5N | 3 | Fabric tears |

**4.3 Whole suit requirements** — **Result**

Protective clothing against infective agents shall fulfil the relevant requirements of EN 340 (replaced by EN ISO 13688) and the whole suit requirements specified in the relevant standard for chemical protective clothing (see Table 5). — Pass (See II-3)

The materials and design used shall not cause skin irritation nor have any adverse effect to health. — (See II-1)

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**II-3 Test standard: EN 13034:2005+A1:2009**
**Protective clothing against liquid chemicals. Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)**

## Section 4 - Performance classification of materials

### EN 14325:2018 Protective clothing against chemicals

Test Methods and performance classification of chemical protective clothing materials, seams, joins and assemblages.

| Clause | | Test Method | | Result | Class | Comment |
|---|---|---|---|---|---|---|
| 4.2 | Pre-conditioning (5 cycles of cleaning) | Not applicable Limited Use | | -- | -- | -- |
| 4.4 | Abrasion Resistance | EN 530 Method 2 | | >10 Cycles (Visual assessment) | unclassified | Moderate abrasion damage with small tears observe of 0.5mm diameter |
| 4.7 | Trapezoidal tear resistance | EN ISO 9073-4 | | A=45N<br>B=47N | 3 | |
| 4.9 | Tensile strength | EN ISO 13934-1 | | A=71.2N<br>B=84.9N | 2 | |
| 4.10 | Puncture resistance | EN 863 | | 7 N | 1 | |
| 4.12 | Repellency to liquids | EN ISO 6530 | | | | |
| | | | 30% H2 SO4 | 94.7% | 3 | |
| | | | 10% NaOH | 96.4% | 3 | |
| | | | o-Xylene | 95.6% | 3 | |
| | | | Butan-1-ol | 96.1% | 3 | |
| 4.13 | Penetration to liquids | EN ISO 6530 | | | | |
| | | | 30% H2 SO4 | 0.0% | 3 | |
| | | | 10% NaOH | 0.0% | 3 | |
| | | | o-Xylene | 0.0% | 3 | |
| | | | Butan-1-ol | 0.0% | 3 | |

## Section 4.2 - Performance requirements for seams joins and assemblages

| Clause | | Test Method | Result | Class | Comment |
|---|---|---|---|---|---|
| 5.2 | Pre-conditioning (5 cycles of cleaning) | Not applicable Limited Use | -- | -- | -- |
| 5.5 | Seam Strength | EN ISO 13935-2 | Leg seam = 108.6N<br>Arm seam = 103.3N<br>Front seam = 121.5N<br>Rise seam = 123.8N | 3 | Fabric tears |

## Section 5 - Performance requirements for whole suit

## Testing in accordance with ISO 17491-4; Determination of resistance to penetration by liquids in the form of a light spray (mist test)

Test Method: The test method used was the total inward leakage method defined in ISO 17491-4 The standard calls for the testing to be carried out using three suits.

Compliance limits are specified in EN 13034:2005 + A1:2009 for type 6 clothing.

The physical dimensions of wearer(s) are shown below;

| Wearer | Height (cm) | Chest (cm) | Suit Size |
|---|---|---|---|
| Steven Kowal | 175 | 102 | XL |

Undergarments as detailed in ISO 17491-4 and a “Sontara” absorbent suit were worn directly under the test garment.

The device is a white material one piece coverall incorporating elasticated cuffs, ankles, waist and hood. There is a double action zip at the front of the suit which runs from crotch to the neck and is covered during use by a flap which is sealed onto the suit material by means of integral double sided adhesive tape.

At the request of the client the coveralls were taped onto a scott “promask” full face mask, wellington boots and rubber gloves.

The wearers were dressed in accordance with the manufacturer’s dressing procedures.

Test Results:
In response to the question “does the suit fit”, the test subject answered “Yes”.

After testing in accordance with the practical movements defined in BS EN13034 for type 6 clothing no damage was observed on the suit.

Surface tension measurements of the test solution were recorded in the reservoir and at the nozzle before and after testing and these ranged from 50.0 to 51.5Nm-1x10 -3 and 50.6 to 51.3Nm-1 x10-3 respectively.

The temperature measurement in the test chamber before and after testing and these ranged from 23.6 to 25.7°C

A Leakage stain was observed at the left rear waist area on the dosimeter suit of the first suit tested.

No leakage staining was observed on the dosimeter suits of the other two suits tested.

Leakage results in terms of area of leakage stains(s) on the dosimeter suit as a ratio of the calibration stain are shown in the following table.

Leakage of liquid into clothing

| Suit number | (1) Calibration of stain ($cm^2$) | (2) Total leakage stain ($cm^2$) | Ratio of (2) to (1) |
|---|---|---|---|
| 1 | 8.27 | 6.55 | 0.79 |
| 2 | 8.27 | 0 | -- |
| 3 | 8.27 | 0 | -- |

Assessment of Compliance

EN 13034:2005 + A1:2009 for type 6 clothing states that “All suits shall pass the test, i.e. the total area on any one undergarment of each suit shall be less than or equal to three times the total calibrated stain area”

For this suit type, the penetration staining was recorded on suit number 1 and was measured as 6.55cm. This stain is 0.79 times the calibration stain of 8.27cm².

Therefore the sample complies with the requirements of EN13034 for type 6 clothing.

*** End of Report ***