

MANUFACTURING TECHNICAL FILE

FOR MEDICAL DEVICES DIRECTIVE 93/42/EEC

*Type of MDD: DISPOSABLE PP ISOLATION GOWN,
CAP, SURGICAL MASK, SHOES COVER*

Reference (s): Q/SF2018A3

COMPANY NAME & ADDRESS

Safeway Industry Healthcare
No.106, Changan Road, Changshangkou, Xiantao, China

SUMMARY

- I. MEDICAL DEVICES IDENTIFICATION
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- VIII. CLINICAL EVALUATION AND CLINICAL DATA OBTAINED

Writer

Name Cai ZhiCao

Position General Manager

Signature:

Date: 2018-06-20

Change History

Version	Change History		Originator	Effective Date
1	1	Corrected MDD because of typo	蔡志超	2017-11-20
2	1	Add "DECLARATION OF CONFORMITY"	蔡志超	2018-2-20
	2	Improve "PACKAGE", add "label" on this part		
	3	Add "EUROPEAN HARMONIZATION AND INTERNATIONAL STANDARD LIST"		
3	1	Add "CLINICAL EVALUATION AND CLINICAL DATA OBTAINED"	蔡志超	2018-6-20

I. MEDICAL DEVICES IDENTIFICATION

1. Type of MDD / EN standard(or basic requirements):

MDD 93/42/EEC CLASS I

2. Trade Mark :

No, OEM

3. TYPE Name :

DISPOSABLE POLYSPUNBOND POLYPROPYLENE ISOLATION GOWN, CAP, SURGICAL MASK,
SHOES COVER WITH VARIED COLORS

4. COLOR AVAILABE:

YELLOW, GREEN, BLUE, WHITE, PINK

5. Production plant(s) (manufacturing place) :

Company name Safeway Industry Healthcare

- Address: No.106,Changan Road, changshangkou, Xiantao China
- Phone +86-728-2511818
- Email : caizm@safe-way.net

II. DECLARATION OF CONFORMITY

Declaration of Conformity

Safeway Industry Healthcare

Add: No.106,Changan Road, changshangkou, Xiantao China

Product Name: Non Sterilized Non-woven Fabric Isolation Garment, Coats, Shoe Covers

NQA Code: 91429004MA49076Q2N

Certificate Number: 45442

Conformity Assessment Route: ISO 13485: 2016.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

Medical Device Directive: The object of the declaration described above is in conformity with the Council Directive MDD 93/42/EEC.

Standard Applied: All applicable harmonised standard (published in the official journal of the European Communities).

III. PRODUCTS DESCRIPTION

1. GENERAL DESCRIPTION

Disposable Polyspunbond polypropylene isolation gown, cap, surgical mask and shoes cover with variant colors yellow, green, blue, pink and white for single use by operating room personnel or general health care workers for protection against microscopic organisms, body fluids and particulate.

2. General Picture



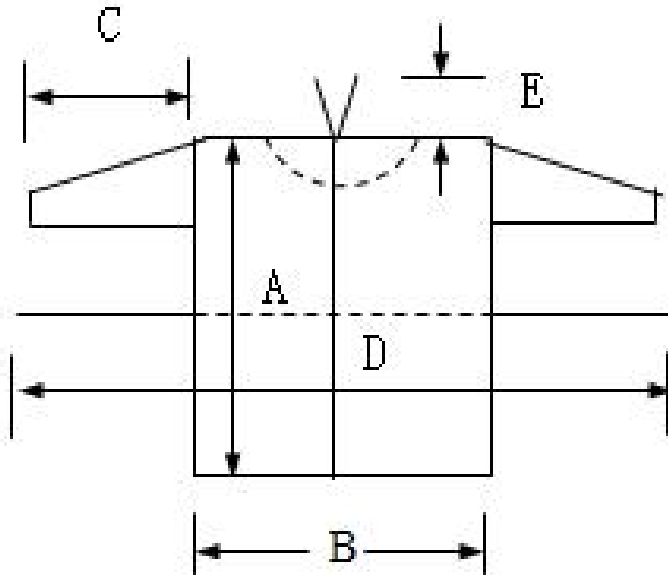
3. LIFE TIME:

5 years after production

4. SIZE DESIGNATION (EN 340)

Dimensions in centimeters

(Applied gown only)



	UNI SIZE	EXTRA LARGE SIZE
A Gown Height	113cm±1.5cm	126cm±1.5cm
B Chest	67cm±1.5cm	76cm±1.5cm
C Sleeve	56cm±1.5cm	56cm±1.5cm
D Belt tie	171cm±5cm	183cm±5cm
E Cuff	30cm±5cm	35.6cm±5cm

5. MATERIALS

Fabric: (Applied cap)	Spunbond Polypropylene from 10g-20g; color available: white, yellow, green, blue, pink
Elastic:	Latex free spandex elastic
Seams:	Latex free Polyester thread

Fabric: (Applied to shoes)	40g PP, with or without anti-slip coated, color available: white, yellow, green, blue, pink
Elastic:	Latex free spandex elastic
Seams:	Latex free Polyester thread

Fabric: (Applied gown)	PP, PP/PE or SMS from 20g-40g, ; color available:: white, yellow, green, blue, pink
Elastic:	Latex free spandex elastic

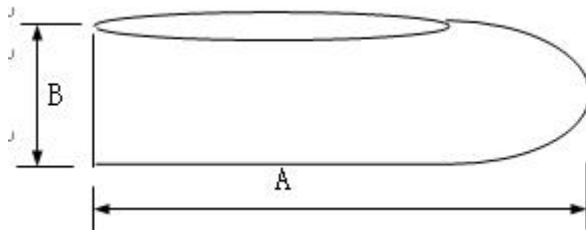
Seams:	Latex free Polyester thread
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Fabric: (Applied to surgical mask)	Three layers, outer layer: 18g PP, media layer: 22g PP, inner layer 25g PP: color available: white, yellow, green, blue, pink
Head strap	Ear-loop with elastic & PP band ties for choice
Nosepiece	Aluminum
Elastic:	Latex free elastic
Seams:	Latex free Polyester thread

Note: All materials are nickel free

Dimension in centimeters:

(applied to shoes cover)

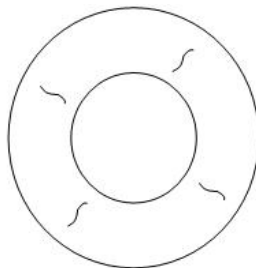


Item Size	Shoes Length A	Heel height B	Opening of shoes	Stretch of opening
Small	38cm	15cm	11cm	23cm
Large	41cm	17cm	11cm	25cm

Fabric: (Applied to shoes cover)	Spunbond Polypropylene from 20g-50g; color available: white, yellow, green, blue
Anti-slip coated	PP
Elastic:	Latex free spandex elastic
Seams:	Latex free Polyester thread

Dimension in centimeters:

(applied to cap)

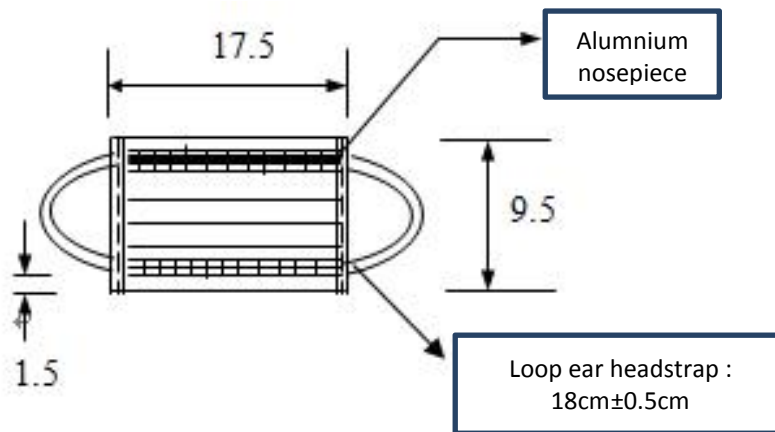


Item Size	Normal	Stretch
21"	7.5"±1.5"	21"±1"
24"	8"±1.5"	24"±1"
27"	9"±1.5"	27"±1"

Fabric: (Applied cap)	Spunbond Polypropylene from 10g-20g; color available: white, yellow, green, blue, pink
Elastic:	Latex free spandex elastic
Seams:	Latex free Polyester thread

Dimension in centimeters:

(applied to cap)



Fabric: (Applied to surgical mask)	Three layers, outer layer: 18g PP, media layer: 25g PP, inner layer 25g PP: color available: white, yellow, green, blue, pink
Head strap	Ear-loop with elastic & PP band ties for choice
Nosepiece	Aluminum
Elastic:	Latex free elastic
Seams:	Latex free Polyester thread

Note: All materials are nickel free

IV. PACKAGE

1. Packing:

Caps: 100pcs/bag or box, 10 bags or boxes per carton




Overshoes, 100pcs/bag or box, 10 bags or boxes per carton

Gowns: 10pcs/ bag, 10 bags per carton

Surgical mask: 50pcs/box, 20boxes per carton

Note: the package and marking can be adjusted on customers' request.

2. Label:

DISPOSABLE ISOLATION GOWN		
23 gram PP, Elastic Cuff, 110X140cm,Green		
10pcs/bag, 100pcs/cs		
Batch NO. (customer PO# or Manufacture Date)		
Made in China		
Bar code		
Manufacture address: No.106,Changan Road, changshangkou, Xiantao, China		
		

2.1 For different products there information on the label are unfixed: product name, product code, specification, sterilization method, products quantity, etc.

2.2 Storage method: Stored in cool, dry and ventilated locations. Far away from fire, sunshine and rain.

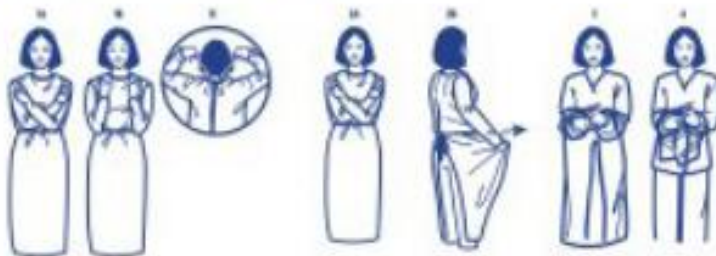
V INSTRUCTION FOR USE

A: Gowns donning and removal instruction

DONNING/PORT/VESTIR



REMOVAL/RETRAIT/QUITER



B: Surgical mask user instruction

WARNING!!!

This respirator helps protect against certain particulate contaminants but does not eliminate exposure to or the risk of contracting any disease or infection. Misuse may result in sickness or death. For proper use, see supervisor, or User Instructions, or call SAFE WAY INDUSTRY (WUHAN) CO., LTD

WARNING: Surgical mask, when worn properly may reduce potential exposure of the wearer to blood and body fluids but do not eliminate the risk of contracting any disease or infection.

IMPORTANT

Before use, the wearer must read and understand these User Instructions. Keep these instructions for reference.

DESCRIPTION

The flat surgical masks are designed to help provide respiratory protection for the wearer. It is fluid resistant, disposable and may be worn in surgery. This product contains no components made from natural rubber latex.

INTENDED USE:

The flat surgical masks are intended for single use by operating room personnel or general health care workers for protection against microscopic organisms, body fluids and particulates. These would include use as procedure mask, isolation mask or dental face mask.

CONTRAINDICATIONS:

Not for industrial use. Not for use with beards or other facial hair that prevents direct contact between the face and the sealing surface of the respirator.

USE INSTRUCTIONS:

1. Before use for respiratory protection, a written respiratory protection program must be implemented meeting all requirements of OSHA 29 CFR 1910.139 and/or 1910.134 such as medical evaluation, training and fit testing. In Canada, CSA standard Z94.4 requirements must be met.
2. Filtering face pieces are to be inspected prior to each use to assure there are no holes in the breathing zone other than the punctures around staples and no damage has occurred. Enlarged holes resulting from ripped or torn filter material around staple punctures are considered damage. Immediately replace respirator if damaged.
3. Discard after every use when used for surgical procedures.
4. Perform a User Seal Check prior to each wearing. To check the respirator-to-face seal, place both hands completely over the respirator and exhale. Be careful not to disturb the position of the respirator. If air leaks around nose, readjust the nosepiece as described in step 5.
5. If air leaks at the respirator edges, work the straps back along the sides of your head. If you CANNOT achieve proper seal, DO NOT enter the isolation or treatment area. See your supervisor.

FITTING INSTRUCTION



! Pinching the nosepiece using one hand may result in improper fit and less effective respirator performance. Use two hands.

REMOVAL INSTRUCTION

See step 2 of Fitting Instructions and cup respirator in hand to maintain position on face. Pull bottom strap overhead. Still holding respirator in position, pull top strap overhead and remove respirator.

VI. TEST AND CONTROL MEANS

Describe rapidly test and control means implemented by the manufacturer for the gown, surgical mask, cap and shoes cover.

Component	Type of control or test	Frequency	Control or test facilities
Incoming Fabric	Q'ty, size, color, mass and apperance check	10pcs@ batch	Visual check and ruler
Fabric cutting	Size check, surface clear	Every 2 hours	Visual check and ruler
Sewing	Stitch according to customer request without leakage, wrong sewing	Every 2 hours	Visual check
Ultrasonic welding (applied to surgical mask)	No missing welding, no welding hole	Every 2 hours	Visual check
Sticking Nosepieces and headstrap (applied to surgical mask)	Nosepiece and headstrap attached to surgical mask tightly, no stapped hole or welded hole	Every 2 hours	Viusal check
FINISHED PACKAGE			
Surface quality check	Size, color, mass check, surface clear without dirt, marking clear and correct	10pcs @ batch	Visual check and weight balance, ruler
Head strap (applied surgical mask only)	Elasticity and force check>9N	10pcs@batch	Visual check and force tester

VII. EUROPEAN HARMONIZATION AND INTERNATIONAL STANDARD LIST

No.	File No.	File Name
1	MDD 93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
2	MDD 89-686-EEC	The Personal Protective Equipment devices
3	ISO 13485:2003	Medical devices -- Quality management systems -- Requirements for regulatory purposes
4	EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical device---part 1:evaluation and testing
5	EN ISO 10993-4:2009	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
6	EN ISO 10993-5:2009	Biological evaluation of medical device---part 5:Test for in vitro cytotoxicity
7	EN ISO 10993-7:2008/AC:2009	Biological evaluation of medical devices, Part 7: Ethylene oxide sterilization residuals
8	EN ISO 10993-10:2010	Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity
9	EN ISO 10993-12: 2012	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
10	EN14126:2005	Protective clothing - Performance requirements and test methods for protective clothing against infective agents
11	EN ISO 16604	Clothing for protection against contact with blood and body fluids - Determination of resistance of protective clothing materials to penetration by blood - borne pocthogens - Test method using Phix - 174 Bacteriophage
12	EN ISO 22610	Clothing for protection against infections against - Test method for resistance to penetration by biologically contaminant dust through protective clothing materials

13	EN ISO 22612	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.
14	EN 980:2008	Symbols for use in the labeling of medical devices
15	ISO 9001:2008	Quality management system – Requirement
16	ISO 2859-1:1999	Sample procedures and tables for inspection by attributes-Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
17	EN ISO 14971:2007	Medical devices—Application of risk management to medical devices
18	EN ISO 14155-2011	Clinical investigation of medical devices for human subjects. Good clinical practice
19	EN 14079:2003	Non-active medical devices—Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze
20	BS EN 1644-1:1997	Test methods for nonwoven compresses for medical use Part 1-Nonwovens used in the manufacture of compresses
21	BS EN 1644-2:2000	Test methods for nonwoven compresses for medical use Part 2- Finished compresses
22	BS EN 14683:2005	Surgical masks - Requirements and test methods

VIII. CLINICAL EVALUATION AND CLINICAL DATA OBTAINED

1. According to the requirements of EN14126, Check item and check standard are as follows:

Item	Test Standard
Wet-Penetration	EN ISO 22610/SOP12-001
Dry-Penetration	EN ISO 22612/SOP12-011
Viral Penetration	EN ISO 16604/SOP12-013

2. Conclusion:

According EN 14126 class 2: Resistance to penetration by infective agents due to mechanical contact with substances contaminated liquids (part 4.1.4.2.).

According EN 14126 class 3: Resistance to penetration by contaminated solid particles (part 4.1.4.4.).

According EN 14126 class 4: Resistance to penetration by contaminated fluid with bacteriophage (part 4.1.4.4.).

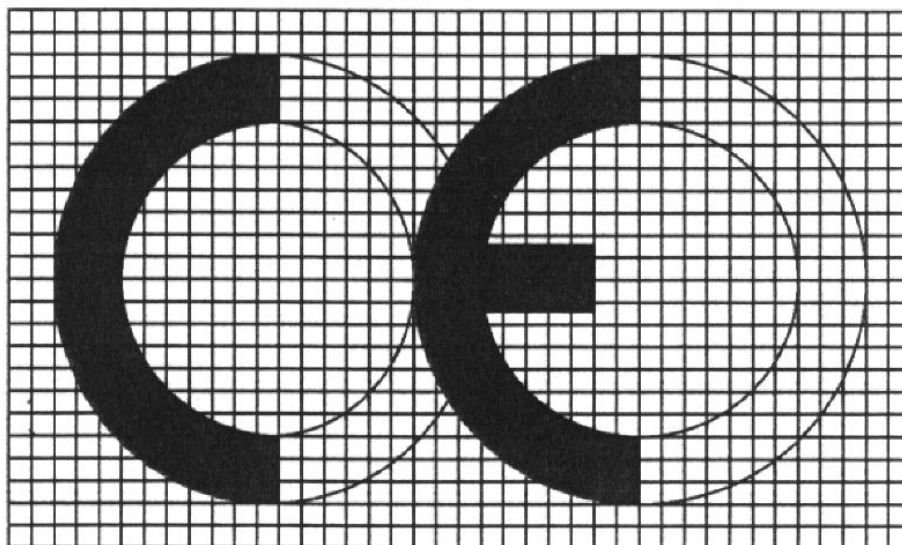
Qualification is defined as that all above-mentioned items meet the requirement. It is unacceptable when one item or more do not meet the requirement, and it can not be put into production. All raw materials of CE products should be qualified before it is put on the market.

3. Clinical data:

SPP Disposable products were introduced many year ago and have now become the widely used products. The product quality gained good appraise in foreign market. All products made by Everbright, Market reaction of the products is good. Please see the Clinical Evaluation of Disposable products for detail information.

ANNEX N°3

CE Graphic



The vertical dimension of CE marking is 10mm.