SC Health

Here for your Health

PPE - Personal Protective Equipment

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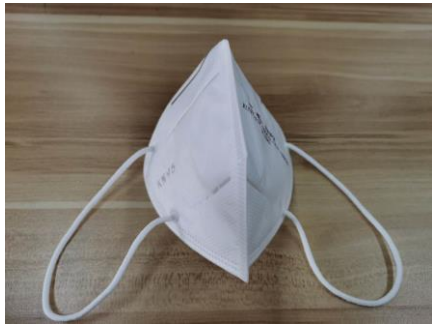
Personal Protective Equipment

- KN95 Mask
- 3-Ply Disposable Mask
- Protective Face Shield
- Sanitizer Gel

KN95 Mask



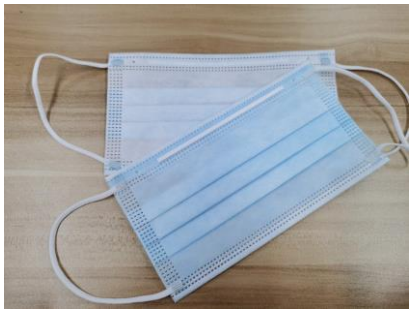
Specification Sheet		
Product Name: KN95 Folding Mask	HS Code : 3926209000	Page 1/1
Product Type:Disposable Face Mask		
1. Photo or Drawing		

2.Material	
1st layer: PP non-woven fabrics	50g
2nd layer: Hot-air cotton non-woven fabric	45g
3rd layer: Melt blown fabric	25g(BFE99)
4th layer:PP non-woven fabrics	30g

4.Packing requirements	
Carton size(cm)	68*43.5*4 3 (±0.5cm)
Packing method	5pcs/bag, 20pcs/box,1000pcs/ctn
Gross weight	6.8kg/ctn(±0.5kg)
Net weight	5.7kg/ctn(±0.5kg)

5.Remarks
*Certificated by CE FDA
*The protective face shield meets the standards as below
A : Made of high quality material and very skin friendly
B : Suitable for respiratory protection,Effectively resist flu and pollen
C : Not recommended for children under three years old due to low vital capacity
D : For one-time use,it should be treated as medical waste

3-Ply Disposable Mask



Specification Sheet		
Product Name: Disposable 3-layer protective mask	HS Code : 3926209000	Page 1/1
Product Type:Disposable Face Mask		
1. Photo or Drawing		
 		
2.Material		
1st layer: PP non woven	25g SSS Level	
2nd layer: Filter paper	25g	
3rd layer: PP non woven	25g SSS Level	
3.Size&Color		
Adult:	17*9.5cm	
Weight :	3.2g(±0.1g)/pcs	
Color :	Whitr/Blue	
4.Packing requirements		
Carton size(cm)	58*40*28cm(±0.5cm)	
Packing method	50pcs/box,2000pcs/ctn	
Gross weight	8.4kg/ctn	
Net weight	7.6kg/ctn	
5.Remarks		
*Certificated by CE FDA		
*The protective face shield meets the standards as below		
A : Made of high quality material and very skin friendly		
B : Suitable for respiratory protection,Effectively resist flu and pollen		
C : Not recommended for children under three years old due to low vital capacity		
D : For one-time use,it should be treated as medical waste		

Mask Company FDA & CE

Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

[redacted]

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

[redacted]

FDA

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D376689	KHA	[redacted]	Single used protective mask with three layers, M1, M2, ME1, ME2, MKC, MKF

CCT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CCT makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. CCT assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. CCT is not affiliated with the U.S. Food and Drug Administration.

[redacted]

Chief engineer
Issued: 03/21/2020
Expiration Date:12/31/2020

CCT TESTING TECHNOLOGY CO., LTD. CCT Testing Service

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Review Report –审查报告–검토 보고서– Rapport d'Evaluation

Form QAT_10-M06, version 00, effective since March 25th, 2020

CE Documentation Review

ENTE CERTIFICAZIONE MACCHINE ECM let's be your partner

[redacted]

Holder: [redacted]

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product: Single used protective mask with three layers (Not Sterile)

Model(s): M1-1,M1-2,M1-3,M1-4,M2-1,M2-2,M2-3, M2-4,ME1-1,ME1-2,ME1-3,ME2-1,ME2-2, ME2-3,MKC1,MKC2,MKC3,MKC4,MKC5, MKF1,MKF2,MKF3,MKF4,MKF5

Classification: Class I (Not Sterile) (accordingly to the Manufacturer's declaration)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Date of issue 28 March 2020
Approver
ECM Service Director
Luca Redonni

Expiry date 27 March 2025
Technical Expert
Amanda Bonfa

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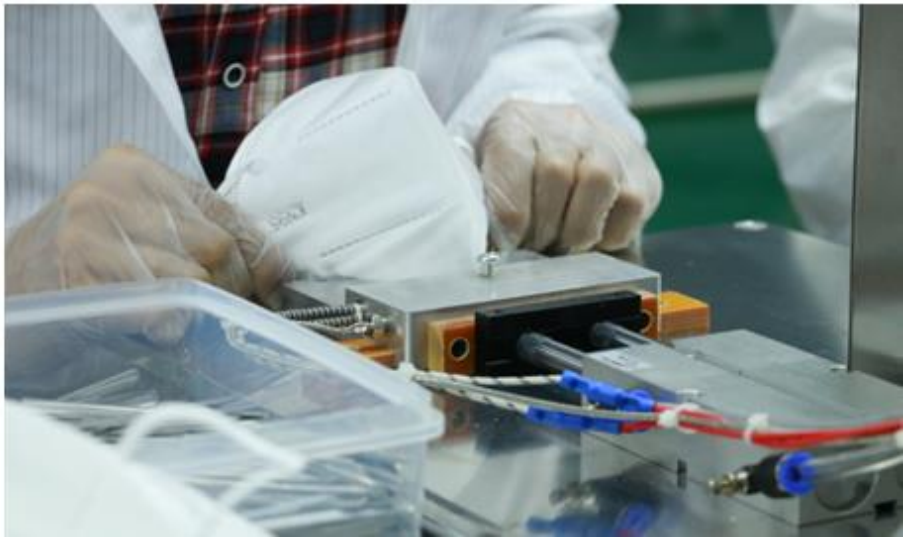
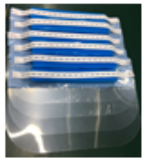
Mask Company Office & Workshop

Mask Company Workshop



Mask Company Workshop

Protective Face Shield

Specification Sheet			
Product Name: Disposable Protective Face Shield	**HS Code:3926.90.90.90**		**Page 1/1**
1. Photo or Drawing			
			
2.Size and Material requirements.			
Lens Material	PET(Anti-fog)		
Dimensions	34*22 cm	**Tolerance**	±0.5cm
Attachment	With blue color sponge, white elastic band	**Thickness of Lens**	0.20±0.02mm
3. Packing requirements.			
Carton size(cm)		42*65*45CM (±0.5cm)	
Packing method		1pcs/bag, 250bags/ctn	
4. AQL standard and essential checking list			
Minor issues within tolerance			
A. For the size or dimensions: ±0.5cm			
B. For the thickness: ±0.02mm for layer			
C. Slight color difference of Sponge and slight scratch in lens is allowed.			
Critical issues out of tolerance			
A. Debrises are not allowed in the polybag.			
B. Unfinished products were packed.			
5. Remarks			
*Certificated : CE certificate Standard: EN149 related to CE Directive(s): R 2016/425 (Personal Protective Equipment)			
*The protective face shield meets the standards as below			
A. Made of clear plastic and provides good visibility			
B. Adjustable band to attach firmly around the head and fit snugly against the forehead			
C. Completely covers the side and length of the face			
D. Could be reused after disinfection			

Face Shield Company CE Certificate

Certificate – Сертификат – 證明書 – Certificat – □ □ □ – شهادة

Form QAT_10-M04, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 2G200320T.FGP0U13

Certificate's Holder: [redacted]

Certification ECM Mark: European Community – Type Approved

Product: Disposable protective face shield

Model(s): FS2001, FS2002, FS2003

Verification to: Standard: EN149

related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

[redacted]

CE

The manufacturer is responsible for the CE Marking process. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.2 available at: www.entecerma.it

Issuance date: 20 March 2020

Expiry date: 19 March 2025

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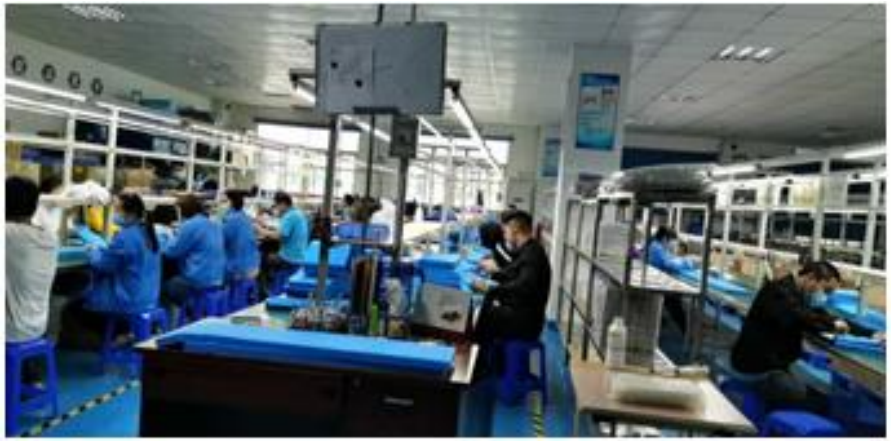
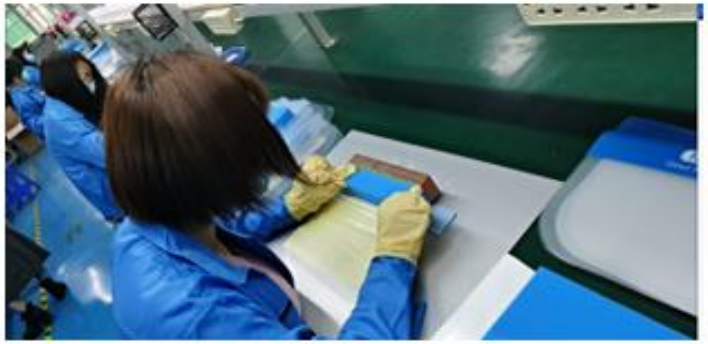
Face Shield Company Office & Workshop



Face Shield Company Workshop



Sanitizer Gel

Specification Sheet		
Product Name: Sanitizer Gel	HS Code:3401.30.00	Page 1/1
Product Type: 75% Alcohol Based Sanitizer Gel		

1. Photo or Drawing

2.Ingredients

Alcohol,Aqua,Glydcerin,Aloe Barbadensis Leaf Extract,Acrylates/c10-30 Alkyl Acrylate Crosspolymer,Triethanlamine.

3.Packing requirements

Size	ctn Dim.(cm)	Units/ Carton	Weight(kg)	Load/40HQ
50ML	54.1*23.7*18.8	200	10.9	250,000
100ML	41.5*25.5*28	120	14	180,000
500ML	40*32.5*18.5	20	11	42,000

4.Directions

Squeeze gel onto your palm and massage your hans together until dry.

5.Warning:Flammable

Keep away from the source if fire and flame

6.Remarks

*Certificated by CE FDA

*For external use only.

A : Keep out of the reach of chidren.

B : Use only under adult supervision.

C : Non staining,may discolor certain fabrics.

Gel Factory FDA & CE

Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

[redacted]

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

[redacted]

Owner/Operator Number: [redacted]

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D375548	LRJ	Disinfectant, medical devices	INSTANT HAND SANITIZER, 50ml,60ml,100ml,250ml,300ml,500ml,1000ml

CCT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CCT makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. CCT assumes no liability to any person or entity in connection with the foregoing.

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Chief engineer
Issued: 03/18/2020
Expiration Date:12/31/2020

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Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Form QAT_10-M04, version 00, effective since March 25th, 2020

RoHS
Certificate of Compliance

No. [redacted]

Certificate's Holder: [redacted]

Product: Instant Hand Sanitizer
Model(s): 30ml; 50ml; 60ml; 100ml; 250ml; 300ml; 500ml; 1000ml

Verification to: Standard: [redacted]

Related to Directive(s):
2011/65/EU amended by 2015/863/EU Restriction of the use of certain hazardous substances (RoHS)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

CE

The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 30 March 2020
Expiry date: 29 March 2025

Reviewer
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Sanitizer Gel Company Office & Workshop

Sanitizer Gel Company Workshop