

MSK-1000

Specifications:

Item Code	MSK-1000
Description	Ordinary protection mask 1000 ct
Case Pack	20/50
Case Cube (CFT)	1.36
Case Weight (lbs)	10.60
Case Dimensions	21x8x14
TlxHl	10x6
Cases per Pallet	60
40HQ Case Qty (Floor Loaded)	1764



Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

G [REDACTED]
G [REDACTED]
Road NO.15.

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

Shenzhen HTT Technology Co., Ltd.

Owner/Operator Number: 10064980



Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D380441	LYU	ACCESSORY, SURGICAL APPAREL	Disposable Medical Face Mask

HTT 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. HTT 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. HTT 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. HTT is not affiliated with the U.S. Food and Drug Administration.



Kevin Yang
 Chief engineer
 Issued: 03/25/2020
 Expiration Date: 12/31/2020

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Mask material		
Item	Data	Color
Filter layer-white meltblown	175mm/25g	Natural color
Ear rope	Nylon + Spandex	White
Bridge of nose	Iron + other	Natural color
Outer layer: SS non-woven fabric	175mm/25g	Blue
Inner layer: SS non-woven fabric	195mm/25g	White
ASTM PERFORMANCE	LEVEL 1	
CE testing standards	EN149	
Low Fluid Resistance:	80mmHg	
Filtration Efficiency:	BFE ≥95%	
	PFE ≥95%@0.1 micron	
Breathability-Delta P:	<4.0 mm H2O/cm2	
Flame Spread:	Class 1	
Inspection Standard: T/CTCA 7-2019		
Test items	Testing requirements	
Formaldehyde content / (mg/kg)	≤20	
pH value	4.0~7.5	
Ethylene oxide residue/ (μg/g)	≤10	
Bacterial filtration efficiency (BFE)%	≥95	
Particulate matter filtration efficiency (PFE)%	≥80	
Ventilation resistance /Pa	≤80	
Breaking strength of the mask belt and the joint between the mask belt and the mask body /N	≥10	
Microbial index:	Coliform: Not allowed to be detected	
	Pathogenic pyogenic bacteria: Not allowed to be detected	
	Total fungal colonies: ≤100 (CFU/g)	
	Total bacterial colonies: ≤200 (CFU/g)	
Field of view under the mask	≥60°	