

INSPECTION REPORT



Checklist for Surgical/Medical Masks (Face Masks) for the German Federal Ministry for Health

Manufacturer / Supplier: ALLMED MEDICAL PRODUCTS CO., LTD
Article: Disposable Medical Face Masks
Order/Contract ID: P000020-173/YGSF-SHA01828670
Location of examination: LinGang YaGu warehouse, Shanghai, P.R. China
Date and time of examination: 2020-6-18
Name of examiner: Jiayin Mao

Overall result:

Fiège Avis	Quantity (pieces) (as available)	Result
P000020-173	1,000,000	GREEN
It's not on the medical export blacklist. It have the registration information of medical surgical masks of national medical products administration. Details: All criteria passed		

Result:

green: OK, no limitations in use, test criteria fulfilled

red: not OK, product failed one or more criteria, detailed failure description documented in table above

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Aspect	Test item	Goal	Result
1 Surgical Masks Documents, Certificates	Certificates according to standards: DIN EN 14683:2019-6 Code: YY/0469-2011 Code: YY/0969-2013 GB19083-2010 (=special Chinese medical mask between surgical mask and FFP 2 mask) GB/T32610-2016 KN95 •	At least one of the mentioned certificates is seen as reliably documented. If no reference to one of the standards is made on the mask, packaging or no certificate is available the compliance is being tested in the test laboratory.	EN 14683:2019
2 Labelling	The packages are labelled in: • English • German Also acceptable if labelled in Chinese only with Chinese Standard Code reference on the packaging.	Packages are readably labelled in one of the mentioned languages and the content of label and description is adequate.	English
3 Packages (individual as well as overall)	Status of the packages	The packages are • dry • undamaged • clean	The packages have been dry, undamaged and clean.
4 Completeness	Number of masks in packages	The number of individual masks in small packages as well as of small packages in whole	50PCS

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			packages (bind) is as specified.	
5	Design and color	Design and color of masks	The design and color of the masks is according to positive samples of verified quality (if available, see sample pictures below). The masks are regularly folded or shaped (see sample pictures below). The fixation of elastic or non-elastic bands is stable. Please check by manual tearing several times. The fixation piece for the nose is easily bendable several times and reliably keeps its shape after bending.	The design has been okay. The masks have been regularly shaped. 5 pcs 10 times tested. No defect has been occurred. Fixation has been good.
6	Medical Masks Design	Design	The Surgical/Medical masks should look similar to the respective pictures below (with closed or open head/ear straps, elastic or non-elastic)	Okay, see enclosed pictures of EUT

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7	Haptics	Haptics of the mask	The haptic feeling of the masks is according to positive samples of verified quality (if available).	The haptic feeling has been good.
8	Shape and wearing	Shape and wearing test of the mask.	The shape and fit of the masks is according to positive samples of verified quality (if available). The internal and external faces of the masks are clearly identifiable/distinguishable. The masks are designed with a structure/shape that does not collapse against the mouth (e.g. duckbill, cup-shaped) The mask fits well and tight on the face (FFP2/3 masks should be in complete contact with the skin, medical masks should cover nose and mouth as well as cheeks) even when moving the head rigidly.	Shape and fit of the mask have been okay. The internal and external faces have been clearly. The masks have not been collapsed against the mouth. The masks fitted well and tight.

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			The fit stays constantly good even during at least five iterations of wearing and removing the mask.	The fit has been stayed constantly.
9	Smell	Smell of the mask	The smell of the masks is according to positive samples of verified quality (if available). No strange or disgusting smells are identified. No mold smell is identified.	Yes, a slight, nondisturbing smell has been detected. Only slight smell has been identified. Mold smell has not been identified.
10	Content / Material	Destructive testing (please cut at least five sample masks from different packages with a scissor and inspect the inside): • Number and material of layers • Haptic and optical inspection of the filter material and the upper and lower layer	A filter fleece with control of the layers and complete filling of the fleece pocket with filter fleece is identifiable. There is at least one filter fleeces layer identifiable. There are no sharp edges visible at the fleece. The fleece should be hydrophobic.	One filter fleece is included, 3 layers in total (see picture) One filter fleece has been identified. Sharp edges haven't been visible at the mask

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			(Test: when water is applied to the fleece, the water should not be soaked up by the fleece or penetrate the fleece but should form water pearls on the fleece; after removal of the water pearls, the fleece should feel dry)	fabric. Yes, the outer skin has been hydrophobic.
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Date and Signature of examiner: Jiayin Mao

Date: June. 18 , 2020

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