

GENERAL INFORMATION			
Service number	200409C18	Date	10 April 2020
Exporting country	P. R. China	Importing country(ies)	Germany
Type of product	N95 face masks		
Importing country/area	(X) European Union () USA/Canada () Other		

In this example, we just verify 2 documents about conformance to EN 149.

MANUFACTURER INFORMATION			
Supplier name	[Confidential]	Supplier address	Unknown
Factory name (local)	[Confidential]	Factory address (local)	[Confidential]
Factory name (English)	[Confidential]	Factory address (English)	[Confidential]
Have we performed a Legal Records Check on the manufacturer?			Yes – see separate report.

PRODUCT INFORMATION, EUROPEAN UNION ONLY		
What is/are the claims of the products? Erase this whole row for non-PPE products	☐ The product protects the environment/patient from contamination by the wearer (It is a Medical Device “MD” under Directive 93/42/EEC and Regulation (EU) 2017/745)	
	☒ The product protects the wearer against microbial and viral infection (It is a Personal Protective Equipment “PPE” under Directive 89/686/EEC and Regulation (EU) 2016/425)	
	☐ The product includes above two functions. (It must comply with both Medical Device Directive “MDD” and Personal Protective Equipment Directive “PPED”.)	
What are the product claims? Erase this whole row for non-PPE products	Bacterial filtration efficiency, %	Not communicated
	Differential pressure, mm H2O/cm2	Not communicated
	Sub-micron particulate filtration efficiency at 0.1 micron, %	Not communicated
	Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	Not communicated
	Flame spread	Not communicated
	Others, please specify	Nil

OVERVIEW	
Is the product labeled as a “medical” product on the Chinese side?	Unknown
Does the manufacturer have a medical license (in China)?	Unknown
Does the manufacturer have a product-specific certification (in China)?	No
Does it seem the manufacturer is capable of <u>exporting</u> out of China ¹ ?	No, they did not produce documents that demonstrate they have the relevant certifications to Chinese standards.
Is the product labeled as a “medical” product on the import country’s side?	Yes
Does the manufacturer have relevant approval/certification for importing country(ies)?	No
Does it seem the manufacturer is capable of <u>importing</u> into [country]?	No, they did not produce documents that demonstrate they have the relevant certifications to European standards.
Does it seem the manufacturer has an appropriate quality management system?	No, they did not produce documents that demonstrate an appropriate quality management system.

VERIFICATION OF DOCUMENT 1	
Checkpoints	Findings & Comments
What is this document?	A laboratory test report
When was it issued?	3 April 2020
When was the testing done?	Unknown
What does it cover?	The manufacturer only for certain products
What standard does it mention?	EN 149:2001+A1:2009
What type of standard is it?	European
What organization issued it? (Name)	Chinese: [Confidential] English: [Confidential]
What organization issued it? (Address)	Chinese: [Confidential] English: [Confidential]

¹ Source: “Order Concerning the Orderly Export of Medical Supplies” - <http://www.mofcom.gov.cn/article/b/e/202003/20200302950371.shtml>

What type of organization is it?	A testing laboratory
What is their accreditation body?	CNAS, a Chinese body.
Is this organization accredited to do such tests on such products?	No. This laboratory is <u>not</u> in the list of approved laboratories for tests on masks. That list is on https://www.cnas.org.cn/english/photoneews/03/902316.shtml . We can't find any mention of "masks" or "medical" in their accredited product scope, and we can find any mention of "filtration" or "leakage" in their accredited test scope.
If it is a certificate: do we also have the corresponding laboratory test results or other supporting documents?	No.
Is there anything in the test results that seems off or unusual?	N/A
Can we verify the legitimacy of this document with the issuing organization?	No. We emailed them and are still waiting for an answer. We called them 3 times during business hours and nobody picked up the phone. We checked on their website at www.[confidential].com and their website confirmed this certificate [include photos of any information below]



中国认可
国际互认
检测
TESTING
CNAS L3764

Confidential

Form No. : Confidential

Testing report

Applicant:*

Confidential

Contacts:*

Address:*

Sample Description:*

KN95 Mask

Style No.:*

/

Application Date:

2020.03.23

Report Date:

2020.04.03

-The contents with "*" is provided by the client .

Top of first page of the test report

VERIFICATION OF DOCUMENT 2	
Checkpoints	Findings & Comments
What is this document?	A certificate
When was it issued?	10 March 2020
When was the testing done?	Unknown
What does it cover?	The manufacturer only for certain products
What standard does it mention?	EN 149:2001+A1:2009
What type of standard is it?	European
What organization issued it? (Name)	ECM – Ente Certificazione Macchine
What organization issued it? (Address)	Via Ca'Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - Italy
What type of organization is it?	A testing laboratory / A government branch
What is their accreditation body?	They are not accredited for PPE, according to https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe .
Is this organization accredited to do such tests on such products?	N/A
If it is a certificate: do we also have the corresponding laboratory test results or other supporting documents?	No
Is there anything in the test results that seems off or unusual?	N/A
Can we verify the legitimacy of this document with the issuing organization?	Yes, on the laboratory's website. However, this testing laboratory (ECM) is <u>not</u> a notified body for PPE. Source: the European Safety Federation (see https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe). The European Safety Federation writes: "any activity performed in regards to the PPE directive has been a voluntary review of technical documentation, and cannot substitute a CE certification in any way". (The voluntary nature of the assessment is also mentioned on the document).

شهادة - 증명서 - Certificate

Certificate of Compliance



No. 4 Confidential

Technical Construction File no. Confidential

Certificate's
Holder:

Confidential

Certification ECM
Mark:



Product: Single-Use Face Mask
Model(s): Ear-hang Type

Verification to: Standard:
EN 149:2001+A1:2009

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

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it.

This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the **CE** Marking:



We attest that a TCF for the **CE** Marking process is in place. Whereas the Manufacturer is Responsible to start the **CE Marking Certification Procedure** through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the **CE** Mark on the product(s).

Certificate - Ce	Date of issue 10 March 2020	Expiry date 09 March 2025
	Chief Manager Marco Morino  	Deputy Manager Amanda Payne  
Ente Certificazione Macchine Srl Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY ☎ +39 051 6705141 📠 +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it		

3 screen captures of the certificate (no pdf download available)

Important notes

Sofeast does not guarantee that the documents we based this work on are accurate, true, or meet the buyer's needs fully.
Sofeast does not accept any liability on this verification work.