

Testing, dokumentasjon og forfalskning av smittevernutstyr

Nettundervisning 3. juni 2020

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Avdeling for smittevern

Oslo universitetssykehus

Innhold

- Definisjoner og kategorisering
- Standarder
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 - Smittefrakker
- Forskrifter og forordninger
- 3. parts kontroll og tilsyn
- Noen eksempler



*A-Magasinet nr. 21
22. mai 2020*

Finn en feil!



Kategorisering

- Smittevernustyr
- Personlig verneutstyr

Standardiseringssystemet

- NS Norsk standard
- EN Europeisk norm
- ISO Internasjonal standard
- NS-EN
- NS-ISO
- NS-EN-ISO

ICS: International classification of standards (emnegrupper)



Harmonisert standard

- Europeisk standard utarbeidet av CEN, CENELEC eller ETSI
- Utarbeidet etter et mandat fra EU (EFTA)
- Brukes av aktuelle aktører for å demonstrere at varer, tjenester eller prosesser er i samsvar med relevante EU-lovgivning

CHAPTER III
CONFORMITY OF THE PPE

Article 14

Presumption of conformity of PPE

PPE which is in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those standards or parts thereof.



ICS emnegruppeoversikt

01	GENERELT. TERMINOLOGI. STANDARDISERING. DOKUMENTASJON
03	SOSIOLOGI. TJENESTER. BEDRIFTSORGANISASJON OG -LEDELSE. ADMINISTRASJON. TRANSPORT
07	MATEMATIKK. NATURVITENSKAP
11	HELSEVESEN, TEKNIKK
13	MILJØVERN. HELSEVERN. SIKKERHET
17	METROLOGI OG MÅLING. FYSISKE FENOMENER
19	PRØVING
21	MEKANISKE SYSTEMER OG KOMPONENTER TIL ALLMENN BRUK
23	HYDRAULISKE SYSTEMER OG KOMPONENTER TIL ALLMENN BRUK
25	PRODUKSJONSTEKNIKK
27	ENERGI- OG VARMEOVERFØRINGSTEKNIKK
29	ELEKTROTEKNIKK
31	ELEKTRONIKK
33	TELEKOMMUNIKASJON. LYD- OG VIDEOTEKNIKK
35	INFORMASJONSTEKNOLOGI. KONTORMASKINER
37	BILDETEKNIKK
39	FINMEKANIKK. SMYKKER
43	KJØRETØYTEKNIKK
45	JERNBANETEKNIKK
47	SKIPSBYGGING OG MARINE KONSTRUKSJONER

Standard Norge

Emnegruppe 11 – helsevesen, teknikk

11.140 Sykehusutstyr

Medisinske ansiktsmasker

Stellefrakker

Smittefrakker

Emnegruppe 13.340 - verneutstyr

13.340.01 Verneutstyr generelt

13.340.10 Verneklær

13.340.20 Hodebeskyttelse

(bl.a. øyevern, hørselsvern, hjelmer)

13.340.30 Åndedrettsvern

13.340.40 Vernehansker

Lover og forskrifter

- Arbeidsmiljøloven
 - Forskrift om konstruksjon, utforming og produksjon av personlig verneutstyr (PVU)
- Lov om medisinsk utstyr
 - Forskrift om medisinsk utstyr
 - Forskrift om bruk av medisinsk utstyr



➔ [Gå til opprinnelig kunngjort versjon](#)

Forskrift om medisinsk utstyr

Dato	FOR-2005-12-15-1690
Departement	Justis- og beredskapsdepartementet, Helse- og omsorgsdepartementet
Publisert	I 2005 hefte 17 (Vedlegg)
Ikrafttredelse	01.01.2006, 01.09.2007
Sist endret	FOR-2020-03-10-258
Endrer	FOR-1995-01-12-25, FOR-1995-08-10-713, FOR-1999-08-20-955
Gjelder for	Norge
Hjemmel	LOV-1995-01-12-6-§3, LOV-1995-01-12-6-§4, LOV-1995-01-12-6-§5, LOV-1995-01-12-6-§6, LOV-1995-01-12-6-§7, LOV-1995-01-12-6-§8, LOV-1995-01-12-6-§9, LOV-1995-01-12-6-§10, LOV-1995-01-12-6-§11, FOR-2001-10-26-1221, LOV-1994-06-16-20-§7, LOV-1929-05-24-4-§10, LOV-1929-05-24-4-§11, FOR-1995-08-04-692, FOR-2003-06-27-793
Kunngjort	03.01.2006
Rettet	01.09.2013 (forordning tilføyd)
Korttittel	Forskrift om medisinsk utstyr

Medisinsk utstyr deles i 4 klasser

- Klasse I
- Klasse IIa
- Klasse IIb
- Klasse III



Klasse 1 medisinsk utstyr som ikke er sterilt og som ikke har målefunksjon krever bare registrering hos competent authority, samsvarserklæring er ikke kontrollert av 3. part

Medisinske ansiktsmasker og usterile engangshansker for medisinsk bruk er medisinsk utstyr i klasse I





NORSK LOVTIDEND

Avd. I Lover og sentrale forskrifter mv.

Utgitt i henhold til lov 19. juni 1969 nr. 53.

Kunngjort 26. juni 2018 kl. 15.35

PDF-versjon 4. juli 2018

22.06.2018 nr. 1019

Forskrift om konstruksjon, utforming og produksjon av personlig verneutstyr (PVU)

Hjemmel: Fastsatt av Arbeids- og sosialdepartementet og Justis- og beredskapsdepartementet 22. juni 2018 med hjemmel i lov 17. juni 2005 nr. 62 om arbeidsmiljø, arbeidstid og stillingsvern mv. (arbeidsmiljøloven) § 3-2, lov 11. juni 1976 nr. 79 om kontroll med produkter og forbrukertjenester (produktkontrollloven) § 4 og lov 16. juni 1994 nr. 20 om tekniske kontrollorgan som har til oppgave å gjennomføre samsvarsvurderinger § 7.

EØS-henvisninger: EØS-avtalen vedlegg II kap. XXII nr. 1 (forordning (EU) 2016/425).

§ 1. Gjennomføring av forordning (EU) 2016/425 om personlig verneutstyr

EØS-avtalen vedlegg II kapittel XXII nr. 1 (forordning (EU) 2016/425) om personlig verneutstyr og om opphevelse av Rådets direktiv 89/686/EØF gjelder som forskrift med de tilpasninger som følger av vedlegg II, protokoll 1 til avtalen og avtalen for øvrig.



Teknisk kontrollorgan/meldt organ (notified body)

§ 4. Teknisk kontrollorgan etter forordning (EU) 2016/425

Et organ som vil bli utpekt som teknisk kontrollorgan skal søke Arbeidstilsynet om dette, jf. forordning (EU) 2016/425 artikkel 21.

Organet skal ved utpekingen oppfylle kravene i forordning (EU) 2016/425 artikkel 24.

Søknaden skal følges av en beskrivelse av den samsvarsvurderingsvirksomheten, den eller de samsvarsvurderingsmodulene og det eller de produktene som organet hevder å være kompetent for, samt et akkrediteringsbevis utstedt av Norsk akkreditering der det bekreftes at organet oppfyller kravene i forordning (EU) 2016/425 artikkel 24.

Notified body behøver ikke være i Norge

Forskrift om konstruksjon, utforming og produksjon av personlig verneutstyr (PVU)

§ 5. *Tilsynsmyndighet*

Arbeidstilsynet, Petroleumstilsynet og Direktoratet for samfunnssikkerhet og beredskap fører tilsyn med at denne forskriften overholdes innenfor sine respektive myndighetsområder.





PPE REGULATION GUIDELINES

**GUIDE TO APPLICATION OF REGULATION (EU) 2016/425 OF THE
EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 9 MARCH
2016 ON PERSONAL PROTECTIVE EQUIPMENT AND REPEALING
COUNCIL DIRECTIVE 89/686/EEC**

1st EDITION – April 2018



Official Journal of the European Union

L 81



English edition

Legislation

Volume 59
31 March 2016

Contents

I Legislative acts

REGULATIONS

- * Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC⁽¹⁾ 1
- * Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC⁽¹⁾ 51
- Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC⁽¹⁾ 99

⁽¹⁾ Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.
The titles of all other acts are printed in bold type and preceded by an asterisk.



REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment

31.3.2016

EN

Official Journal of the European Union

L 81/51

REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 9 March 2016
on personal protective equipment and repealing Council Directive 89/686/EEC
(Text with EEA relevance)



Artikkel 15

EU-samsvarserklæring

1. EU-samsvarserklæringen skal fastslå at det er påvist at de grunnleggende helse- og sikkerhetskravene fastsatt i vedlegg II er oppfylt.
2. EU-samsvarserklæringen skal være i henhold til malen fastsatt i vedlegg IX, skal inneholde elementene angitt i de relevante modulene fastsatt i vedlegg IV, VI, VII og VIII og skal oppdateres jevnlig. Den skal oversettes til det eller de språkene som kreves av den medlemsstaten der PVU-et bringes i omsetning eller gjøres tilgjengelig på markedet.
3. Dersom PVU-et omfattes av flere enn én unionsrettsakt som krever en EU-samsvarserklæring, skal det utarbeides en enkelt EU-samsvarserklæring for alle disse unionsrettsaktene. Erklæringen skal angi hvilke unionsrettsakter den gjelder, herunder henvisninger til hvor de er kunngjort.
4. Ved å utarbeide EU-samsvarserklæringen påtar produsenten seg ansvaret for at PVU-et er i samsvar med kravene i denne forordning.



Utforming av samsvarserklæring

VEDLEGG IX

EU-SAMSVARERKLÆRING NR. ...⁽¹⁾

1. PVU (produkt-, type-, parti- eller serienummer):
2. Navn og adresse til produsenten og eventuelt dennes representant:
3. Denne samsvarserklæringen utstedes på produsentens eneansvar:
4. Erklæringens gjenstand (identifikasjon av PVU-et som gjør det mulig å spore det; kan ved behov omfatte et fargebilde som er tilstrekkelig tydelig til å identifisere PVU-et):
5. Erklæringens gjenstand som beskrevet i nr. 4 er i samsvar med Unionens gjeldende harmoniseringsregelverk: ...
6. Henvisninger til de relevante harmoniserte standardene som er anvendt, herunder standardens dato, eller henvisninger til andre tekniske spesifikasjoner, herunder spesifikasjonens dato, det erklæres samsvar med:
7. Dersom det er relevant: Det meldte organet ... (navn, nummer) ... har utført EU-typeprøving (modul B) og utstedt EU-typeprøvingssertifikat ... (henvisning til sertifikatet).
8. Dersom det er relevant: PVU-et omfattes av framgangsmåten for samsvars vurdering ... (enten typesamsvar basert på intern produksjonskontroll og overvåket produktkontroll med ujevne mellomrom (modul C2) eller typesamsvar basert på kvalitetssikring av produksjonsprosessen (modul D)) ... under tilsyn av det meldte organet ... (navn, nummer).
9. Tilleggsopplysninger:

Undertegnet for og på vegne av: ...

(sted og dato):

(navn, stilling) (underskrift):



Risikokategorier for verneutstyr

ANNEX I

RISK CATEGORIES OF PPE

This Annex lays down the categories of risk against which PPE is intended to protect users.

Category I

Category I includes exclusively the following minimal risks:

- (a) superficial mechanical injury;
- (b) contact with cleaning materials of weak action or prolonged contact with water;
- (c) contact with hot surfaces not exceeding 50 °C;
- (d) damage to the eyes due to exposure to sunlight (other than during observation of the sun);
- (e) atmospheric conditions that are not of an extreme nature.

Category II

Category II includes risks other than those listed in Categories I and III;



Category III

Category III includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health relating to the following:

- (a) substances and mixtures which are hazardous to health;
- (b) atmospheres with oxygen deficiency;
- (c) harmful biological agents;
- (d) ionising radiation;
- (e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C;
- (f) low-temperature environments the effects of which are comparable to those of an air temperature of – 50 °C or less;
- (g) falling from a height;
- (h) electric shock and live working;
- (i) drowning;
- (j) cuts by hand-held chainsaws;
- (k) high-pressure jets;
- (l) bullet wounds or knife stabs;
- (m) harmful noise.



Article 17

Rules and conditions for affixing the CE marking

1. The CE marking shall be affixed visibly, legibly and indelibly to the PPE. Where that is not possible or not warranted on account of the nature of the PPE, it shall be affixed to the packaging and to the documents accompanying the PPE.
2. The CE marking shall be affixed before the PPE is placed on the market.
3. For category III PPE, the CE marking shall be followed by the identification number of the notified body involved in the procedure set out in Annex VII or VIII.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

4. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or other marking indicating the risk against which the PPE is intended to protect.
5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.



Hansker

- Norsk standard NS-EN 455
- Norsk standard NS-EN ISO 374 (inkl. kjemikalier)
- Norsk standard NS-EN 16523-1:2015+A1:2018



Engangshansker for medisinsk bruk

- Norsk standard NS-EN 455-1:2000
- **Her må det foreligge informasjon om verdi for AQL, som må være maksimalt 1,5, helst 0,65.**
- Norsk standard NS-EN 455-2:2015
- Norsk standard NS-EN 455-3:2015
- Norsk standard NS-EN 455-4:2009
- Hvis det også kreves beskyttelse mot kjemikalier, må det være dokumentasjon i henhold til:



ICS 13.340.40 Vernehansker

ICS 13.340.01 Verneutstyr generelt

- **Norsk standard NS-EN ISO 374** (ICS 13.340.40 Vernehansker)
 - NS-EN ISO 374-1:2016
 - NS-EN ISO 374-1:2016/A1 2018 Endring A1
 - NS-EN ISO 374-2:2019
 - NS-EN ISO 374-4:2019
 - NS-EN ISO 374-5:2016
- **Norsk standard NS-EN 16523-1:2015+A1:2018** (ICS 13.340.01 Verneutstyr generelt)



Medisinske ansiktsmasker (munnbind)

ICS 11.140

- Leverandør/produsent bør kunne dokumentere at munnbindet er testet i henhold til:
- **NS-EN 14683:2019+AC:2019**
- Munnbindet skal tilfredsstillere kravet til type II, det vil si en bakteriell filtreringseffektivitet (BFE) på 98 %.

Medisinske ansiktsmasker er medisinsk utstyr klasse I



Krav til kirurgiske munnbind

NS-EN 14683:2019+ AC:2019

Test	Type I	Type II	Type IIR
Bakteriell filtrerings-effektivitet (BFE), %	≥ 95	≥ 98	≥ 98
Differensialtrykk (Pa/cm ²)	< 40	< 40	< 60
Sprutresistens, trykk (kPa)	Ikke krav	Ikke krav	≥ 16 (1,6 m H ₂ O)



Åndedrettsvern

Filtrerende halvmaske (FFP3)

Skal tilfredsstillere kravene til FFP3 i NS-EN ISO 149:2001+A1:2009.

Ved mangel på masker FFP3, er alternativet FFP2. Kravene til FFP2 finnes i samme standard.

Krafttilført (motordrevet) filtrerende åndedrettsvern med hjelm eller hette (PAPR)

Skal tilfredsstillere kravene til TH3P i NS-EN 12941:1998/A2:2008



Åndedrettsvern

Filtrerende halvmaske



Filtrerende åndedrettsvern
fergangsbruk av maske
med utskiftbare filtre



Motordrevet filtrerende åndedrettsvern (PAPR)



	Europa		USA		Kina
Type	FFP3	FFP2	N95	N100	KN95
Standard	EN 149: 2001	EN 149: 2001	NIOSH- 42CFR84	NIOSH- 42CFR84	GB2626-2006
3. parts kontroll	<u>Bemyndiget organ</u> (<u>notified body</u>)	<u>Bemyndiget organ</u> (<u>notified body</u>)	<u>NIOSH</u> <u>FDA</u>	<u>NIOSH</u> <u>FDA</u>	??
Filtreringseffekt	≥99,95%	≥94%	≥95%	≥99,97%	≥95%
Luftmengde	95 l/min	95 l/min	85 l/min	85 l/min	85 l/min
Total lekkasje inn (TIL)*	2 % **	8 % **	Ikke krav	Ikke krav	8 % **
Inhalasjons- motstand. Maks trykkfall	≤ 70 Pa v/30 L/min ≤ 240 Pa v/ 95 L/min)	≤ 70 Pa v/30 L/min ≤ 240 Pa v/ 95 L/min)	≤ 343 Pa	≤ 343 Pa	≤ 350 Pa
Utpustingsmot-stand. Maks trykkfall	≤ 300 Pa	≤ 300 Pa	≤ 245 Pa	≤ 245 Pa	≤ 250 Pa
Utpustingsventil Lekkasjekrav	Ikke krav	Ikke krav	Lekkasje ≤ 30 mL/min	Lekkasje ≤ 30 mL/min	Trykkreduksjon til 0 Pa ≥ 20 sek
Anvendt kraft	Ikke krav	Ikke krav	-245 Pa	-245 Pa	-1180 Pa
CO ₂ nivå	≤ 1 %	≤ 1 %	Ikke krav	≤ 1 %	≤ 1 %



Smittefrakk – Norsk standard = medisinsk utstyr (ICS 11.140.61.020)



Smittefrakker/vernetøy (ICS 13.340.10)

Leverandør/produsent bør kunne dokumentere at smittefrakken er testet i henhold til:

NS-EN 14126:2003 - innbefattet rettelsesblad AC:2004 og de tilhørende standardene:

NS-EN ISO 16604:2004

Her er det 6 ulike klasser (1-6) basert på motstand mot hydrostatisk trykk. Leverandør må oppgi hvilken klasse produkter tilfredsstill

ISO 22610:2018

Her er det 6 ulike klasser (1-6), basert på tid før gjennomtrengning (< 15 min - > 75 min).
Leverandør må oppgi hvilken klasse produkter tilfredsstill

NS-EN ISO 22612:2005

Her er det 3 ulike klasser (1-3), basert på motstand mot penetrasjon av kontaminerte faste partikler (< 15 min - > 75 min) Leverandør må oppgi hvilken klasse produktet tilfredsstill.



Operasjonsfrakker (ICS.11.140)

- Leverandør/produsent bør kunne dokumentere at smittefrakken er testet i henhold til:
- **NS-EN 13795-1:2019**
- Her er det to kategorier når det gjelder barriere/ beskyttelse: Standard performance og High performance, i henhold til testing etter NS-EN ISO 22612, NS-EN ISO 22610 og NS-EN ISO 811. Leverandør må oppgi hvilke krav som er dokumentert for de respektive frakkene, se tabell 1 i NS-EN 13795-1



Noen eksempler



Technical Data Sheet
DASHENG DTC3Z FFP3 NR D
Respirator mask



Features

- Individually sealed for hygiene and carrying convenience.
- Made of non-woven, moisture-proof, non-toxic, non-irritating
- Light weight, soft and comfortable to wear and effortless breathable
- Fold flat respirator with cup-shaped face mask which fit different face shapes.
- Designed to seal to the face of user

Description

- Respiratory Protective Device – Filtering Half Mask
- Tested and CE Approved FFP3 to EN 149:2001+A1:2009
- NIOSH-Approved N95 Particulate Filtering Facepiece Respirators registered CDC list
- Filters at least 99% of airborne particles
- Headband design style
- Ultrasonic welding technology, glue-free and odorless

Specifications

- Material: non-woven fabric
- Color: white
- Type: adult

Packaging



BOX	CTN	Dimension	GW/NW
(PCS)	(BOXES)	(CM/CTN)	(KG/CTN)
20	20	47x43x32	4.5/4



Certificate Number: PPE19161253

EU TYPE-EXAMINATION CERTIFICATE

This is to certify that the Personal Protective Equipment type, in respect of the product detailed on this certificate, has been evaluated and deemed to be in compliance with Regulation (EU) 2016/425 Module B, and the applicable Essential Health & Safety Requirements.

Manufacturer: **Shanghai Dasheng Health Products Manufacture Co Ltd**
No. 228 Shihui Road,
Songjiang,
Shanghai 201613,
China.

Compliance with the applicable Essential Health & Safety Requirements has been demonstrated as above, including examination in accordance with the harmonised standard below:

EN149:2001 +A1:2009

Product description: Respiratory Protective Devices – Filtering Half Masks;

Double Fold Flat Style

DTC3Z, DTC3Z-F, DAC4Z, DAC4Z-F

Date of initial certification: 16th February 2019
Date of current issue: 16th February 2019
Date of expiry: 16th February 2024

A. J. J. J.
Technical Director



INSPEC International Ltd, 56 Leslie Hough Way, Salford, Manchester, M6 6AJ, England. Notified body number 0194

This certificate has been issued in accordance with our standard terms and conditions and subject to INSPEC Regulations and Conditions of Use. This certificate remains the property of INSPEC and may be withdrawn if any of the conditions attached to its issue are not complied with by the certified company.



Product details**Model identification:**

Model	Exhalation Valve	Carbon layer
DTC3Z FFP1 NR D	No	No
DTC3Z FFP2 NR D		
DTC3Z FFP3 NR D		
DTC3Z-F FFP1 NR D	Yes	No
DTC3Z-F FFP2 NR D		
DTC3Z-F FFP3 NR D		
DAC4Z FFP1 NR D	No	Yes
DAC4Z FFP2 NR D		
DAC4Z FFP3 NR D		
DAC4Z-F FFP1 NR D	Yes	Yes
DAC4Z-F FFP2 NR D		
DAC4Z-F FFP3 NR D		

Key:

NR	Non re-useable / limited to single shift use only
D	Dolomite clogging test requirements satisfied

Technical file reference: DSTF Z (TF19161253)**Test reports:** 1.15.10.15**Category:** III

Category III product must also have a certificate demonstrating conformity with Module C2 or D of Council Regulation (EU) 2016/425.

Classification: See above**Accessories or spares:** None

INSPEC International Ltd, 56 Leslie Hough Way, Salford, Manchester, M6 6AJ, England. Notified Body Number 0194

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Current issue: 16/02/19

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Certificate amendment record

Date	Description
16/02/2019	Initial issue

Conditions attached to the issue of this certificate:

1. Marking and instructions have been assessed in the English language only. It is the Manufacturer's/Authorised Representative's responsibility to obtain and supply language versions acceptable to the country where the product is to be sold.
2. Any changes to the product, technical file or quality manual/quality plan shall be immediately notified to INSPEC.
3. The Manufacturer/Authorised Representative shall comply at all times with INSPEC's Regulations governing CE Product Certification.
4. Satisfactory maintenance of certification against module C2 or Module D for category III product.
5. This certificate remains the property of INSPEC and may be withdrawn if any of the conditions attached to its issue are not complied with.
6. This certificate may be copied or reproduced by the certificate holder, complete and without omissions or additions, and in accordance with INSPEC's terms of business.

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Current issue: 16/02/19

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http://www.dashengmask.com/index/index/details/id/152.html Søkeresultater | standard.no Dasheng Health Products ...

Tell: 86+21-57783126 Fax: 86+21-57784148 Address: 228 Shihui Road, Songjiang, Shanghai 201613, China


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DTC3Z FFP3 NR D



- Filters at least 99% of airborne particles.
- Headband design style.
- Ultrasonic welding technology, glue-free and odorless.




LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 89/686/EEC Personal protective equipment				
Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures or modules	Annexes or articles of the directives


Creation Date : 19/04/2019

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 89/686/EEC Personal protective equipment				
Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures or modules	Annexes or articles of the directives
INSPEC International Ltd. 56 Leslie Hough Way, Salford, Greater Manchester M6 6AJ United Kingdom	0194	*Equipment providing general body protection (clothing) against mechanical risks *Equipment providing eye protection *Equipment providing face protection *Equipment providing foot and leg protection *Equipment providing general body protection (clothing) *Equipment providing hand and arm protection *Equipment providing head protection *Equipment providing hearing protection *Equipment providing respiratory protection *Protective equipment against drowning and buoyancy aids *Protective equipment against falls from a height	EC type-examination System for ensuring EC quality of production by means of monitoring EC quality control system for the final product	Art.10 Art.11B Art.11A









https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N... CDC - NIOSH-Approved N9...

 Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

All A-Z Topics
Search NIOSH 
[Advanced Search](#)

The National Personal Protective Technology Laboratory (NPPTL)

NIOSH-Approved Particulate Filtering Facepiece Respirators     

Promoting productive workplaces through safety and health research 

NIOSH-Approved N95 Particulate Filtering Facepiece Respirators

Updated May 20, 2020

Manufacturers Listed Alphabetically – S

The N95 respirator is the most common of the seven types of particulate filtering facepiece respirators. This product filters at least 95% of airborne particles but is not resistant to oil.

This web page provides a table of NIOSH-approved N95 respirators, listed alphabetically by manufacturer. You can select a particular manufacturer by clicking on the first letter of their name on the index below.

There are some products that are approved by NIOSH as an N95 respirator and also cleared by the Food and Drug Administration (FDA) as a surgical mask. These products are referred to as **Surgical N95 Respirators**. [View a definition of Surgical N95 Respirators](#). For your convenience the Surgical N95 Respirators are indicated with the **Model Number/Product Line in bold text followed by (FDA)**. If you have a product you believe is NIOSH-approved and FDA-cleared that does not appear on this list, you will need to check with CDC to determine if NIOSH-approved at 1-800-CDC-INFO (1-800-232-4636) and the FDA Center for Devices and Radiological Health at 1-800-638-2041 for verification of clearance. [View a comprehensive table of Surgical N95 Respirators](#).

***Disclaimer:** The links in this section go to websites outside of CDC/NIOSH and should not be considered as an endorsement of their content, or as a statement of NIOSH policy. The donning procedure and/or user instruction, either on the websites or the PDF version, should not be considered an official endorsement of their content, or as a statement of NIOSH policy.*

https://www.cdc.gov/niosh/index.htm



https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/n95 CDC - NIOSH-Approved N95...


Delta Plus Group [✗] [*S] 86-21-5778-3126	M1200VPC	84A-4471	Yes	M1200VPC [PDF - 247 KB]
Delta Plus Group [✗] [*S] 86-21-5778-3126	M1200VBC	84A-4472	Yes	M1200VBC [PDF - 247 KB]
Delta Plus Group [✗] [*AD] 86-512-66100068	MS6115L / M10N95S	84A-5530	No	MS6115L/M10N95S [PDF - 94 KB]
Delta Plus Group [✗] [*AD] 86-512-66100068	MS6155L / M10N95VS	84A-6766	Yes	MS6155L/M10N95VS [PDF - 90 KB]
Delta Plus Group [✗] [*S] 86-21-5778-3126	DTC3Z M1104C	84A-8150	No	All Models [PDF - 75 KB]
Delta Plus Group [✗] [*S] 86-21-5778-3126	DTC3Z-F M1104VC	84A-8425	Yes	All Models [PDF - 75 KB]
Delta Plus Group [✗] [*AD] 86-512-66100068	6215 / M10N95	84A-8474	No	6215/M10N95 [PDF - 91 KB]
Delta Plus Group [✗] [*AD] 86-512-66100068	6255 / M10N95V	84A-8475	Yes	6255/M10N95V [PDF - 90 KB]
Dentec Safety [✗] 888-533-6832	Softseal-D ADN95V	84A-2011	Yes	Softseal-D ADN95V [PDF - 137 KB]
Dentec Safety [✗] 888-533-6832	Softseal-D ADN95	84A-2012	No	Softseal-D ADN95 [PDF - 137 KB]
Dentec Safety [✗] [*E] 888-533-6832	AD2N95 AD2N95 OV	84A-3323	No	All Models [PDF - 842 KB]
Dentec Safety [✗] [*E] 888-533-6832	AD2N95V	84A-3904	Yes	AD2N95V [PDF - 154 KB]



http://www.dashengmask.com/ Dasheng Health Products ...

Tell: 86+21-57783126 Fax: 86+21-57784148 Address: 228 Shihui Road, Songjiang, Shanghai 201613, China

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DASHENG MASKS SERIES


The company passed the ISO9001 international quality management system certification. Dasheng masks dozens of models for the European standard EN149 and get FFP1, FFP2 and FFP3 quality level certification respectively; dozens of models for AS / NZS 1716 Standards Australia and the United States NEISON, NIOSH N95, N99 standard international certification. Double victory license mesh valve masks and face cloth masks and other national PatentOffice.



太行安全
TAYHAMN

Teknisk Datablad

TAYHAMN FFP2 / KN95 filtermaske
TH2210



Description

- Tested and CE Approved FFP2 to EN 149:2001+A1:2009
- BFE test reach 98.9% (KN95-Test)
- Foldable, easy to store, proprietary 3-panel design accommodates facial movement for wearer comfort.
- Material: with 5 layers (2 layers 50gsm non-woven fabric, 2 layers 25gsm melt-blown fabric KN95 standard; 1-layer dust-proof cotton)
- Low breathing resistance filter technology gives effective filtration with low breathing resistance for consistent high-quality performance
- Sculpted nose panel conforms to the nose and contours of the face and helps improve compatibility with 3M eyewear

Approvals

- TH2210 meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425 EN1492001+A12009
- Evaluation has been carried out in accordance with test reports made by Shanghai MICEZ Equipment Testing Technical Co, LTD Laboratory NO of test reports: MICEZ-20200302PPE
- Products are classified by filtering efficiency and maximum total inward leakage performance (FFP2 and FFP3), also by usability and clogging resistance.
- TH2210 tested Item (Filtration efficiency, leakiness, inhalation resistance, breathing valve air tightness, headband) is comply with the standard of GB 2626-2660 Respiratory protective equipment Self-priming filter anti-particle respirator. Labor protective equipment safety and quality assessment 2018
- Award-winning product quality sampling plan and Approved by National Labor Protection Supplies Quality Supervision and Inspection Center Beijing.

太行安全
TAYHAMN

Applications:

Designed to prevent or reduce dust in the air from entering the human respiratory organs to protect life.

Filtering principle: Filtering dust mainly depends on the middle filter cloth. Because the melt blown cloth has the characteristics of static electricity, it can adsorb positively small particles. Since the fine dust is adsorbed on the original filter, and the original filter is electrostatically charged and cannot be washed, the self-priming filter type anti-particle respirator needs to replace the original filter regularly.

Protection level: KN95, FFP2 FFP3 Filtration Efficiency $\geq 95\%$

Technique Data:

Product Model TH-2210

Items	Standard
Filtration	$\geq 90\%$ (KN95)
Efficiency	$\geq 95\%$ (KN95) $\geq 99.9\%$ (KN100) Gas Flow Test : (85±4) L/min
	Environment Temperature: Humidity: (30±10)%

太行安全
TAYHAMN

Items	Standard Requirement	Test Results
Leakage	Based on the TIL of each action (that is mean 10 people x 5 actions, at least with 46 actions of the 50 actions TIL)	Sample No. Test Result
		11 49 Actions's TIL<11%
		12 49 Actions's TIL<11%
		13 49 Actions's TIL<11%
		14 48 Actions's TIL<11%
	15 48 Actions's TIL<11%	
	Based on the people TIL, 10 testet people at least with 8 people TIL	Sample No. Test Result
		11 9 poeple TIL <8%
		12 9 poeple TIL <8%
		13 9 poeple TIL <8%
14 9 poeple TIL <8%		
15 9 poeple TIL <8%		
Inhalation Resistance	Standard Requirement	Sample No. Test Result
	Each sample's total Inhalation resistance $\leq 350\text{pa}$	16 78pa
		17 78pa
Expiratory Resistance	Standard Requirement	Sample No. Test Result
	Each sample's total Expiratory resistance $\leq 250\text{pa}$	16 24pa
		17 26pa
Air tightness of breathing valve	The following situations must not occur: a) When the pumping flow rate has reached 500 mL/min, the negative pressure of the system < 1180pa:	16 System negative pressure reached 1180pa
		17 System negative pressure reached 1180pa
	The followina situations must not occur: b)The time of	16 >20S

Items	Standard Requirement	Test Results				
Leakage	Based on the TIL of each action (that is mean 10 people x 5 actions, at least with 46 actions of the 50 actions TIL)	<13%	Sample No.	Test Result		
		<11%	11	49 Actions's TIL<11%		
		<5%	12	49 Actions's TIL<11%		
			13	49 Actions's TIL<11%		
			14	48 Actions's TIL<11%		
	Based on the people TIL, 10 testat people at least with 8 people TIL	<10%	Sample No.	Test Result		
		<8%	11	9 poeple TIL <8%		
		<2%	12	9 poeple TIL <8%		
			13	9 poeple TIL <8%		
			14	9 poeple TIL <8%		
	Inhalation Resistance	Standard Requirement Each sample's total Inhalation resistance ≤350pa	Sample No.	Test Result		
			16	78pa		
			17	78pa		
			Expiratory Resistance	Standard Requirement Each sample's total Expiratory resistance ≤250pa	Sample No.	Test Result
					16	24pa
17	26pa					
Air tightness of breathing valve	The following situations must not occur: a) When the pumping flow rate has reached 500 mL/min, the negative pressure of the system < 1180pa:	16	System negative pressure reached 1180pa			
		17	System negative pressure reached 1180pa			
	The following situations must not occur: b)The time of the exhalation valve to return to normal pressure is <20S	16	>20S			
		17	>20S			
	Ordinary Temperature, Ordinary Pressure, realive humidity <75%	Temperature: 24 °C, Ordinary Pressure, Relative humidity: 40%				
		Sample No.	Test Result			
Headband	When each headband, buckle and other adjustment parts of the disposable mask are subjected to a tensile force of 10N for a duration of 10S, There should not be slippage or fracture	18	10N for 10S without slippage or fracture			

These products meet the requirements of the EU Directive 89/686EEC (Personal Protective Equipment Directive) and are CE marked Certification under Article 10, EC Type-Examination and Article 11, EC quality control, has been issued for these products by ICR Co., Ltd., Plac Przymierza 6, 03-944 Warszawa, POLAND



Certificate

NO. ICR Polska/M600201313



Name and address of Certificate owner: Guangzhou Tayhamn Safety Equipment Manufacturing Co., Ltd.
Yonghe Industrial Park, No.1, North Xinsha avenue, Shapu, Xintang town, Zengcheng district, Guangzhou, China

Product name: FACE MASK
Product types: TH2210 TH2210V TH6210C TH6210VC

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 149:2001+A1:2009

The certification process has been carried out in accordance with the program PC.P07.07. Evaluation has been carried out in accordance with test reports made by Shanghai MICEZ Equipment Testing & Technical Co. LTD Laboratory.

NO. of test reports: MICEZ-20200302PPE

Certificate issue date: March 13, 2020

Expiration date: March 13, 2023

The mutual obligations and rights of the certification are regulated by the contract NO. ICR Polska/2020-0118.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.



Rafal Kalinowski
Director: Rafal Kalinowski

Warsaw, 13. 03. 2020

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com



https://ec.europa.eu/growth/tools-databases/nando/index.cfm?f... EUROPA - European Comm... x

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Notifying Authority - Notification procedures

Accreditation Body

Bodies

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Technical Assessment Body
User Inspectorate PED Art. 16


Recognised third-party organisation PED Art. 20
Withdrawn/Expired/Suspended Notifications/NBs


Notified body

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• 0501-0600	• 0601-0700	• 0701-0800	• 0801-0900	• 0901-1000
• 1001-1100	• 1101-1200	• 1201-1300	• 1301-1400	• 1401-1500
• 1501-1600	• 1601-1700	• 1701-1800	• 1801-1900	• 1901-2000
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• 2501-2600	• 2601-2700	• 2701-2800	• 2801-2900	



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English 

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Internal Market, Industry, Entrepreneurship and SMEs

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- Mutual Recognition Agreements
- CETA Protocol on Conformity Assessment
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Bodies Found : 47

Search criteria :
Name : 0001-0100

Withdrawn/Expired/Suspended Notifications/NBs are not displayed in this list, you can find them in the Body module under the hyperlink "[Withdrawn/Expired/Suspended Notifications/NBs](#)"

Body type	Name ▲	Country ▲
▶ NB 0026	VINÇOTTE sa/nv	Belgium
▶ NB 0027	VERENIGING BUREAU VERITAS	Belgium
▶ NB 0028	INSTITUTO DE SOLDADURA E QUALIDADE	Portugal
▶ NB 0029	APRAGAZ A.S.B.L.	Belgium
▶ NB 0035	TÜV Rheinland Industrie Service GmbH	Germany
▶ NB 0036	TÜV SÜD Industrie Service GmbH	Germany
▶ NB 0037	ZÜRICH ENGINEERING	United Kingdom
▶ NB 0038	Lloyd's Register Verification Limited	United Kingdom
▶ NB 0040	BRITISH ENGINEERING SERVICES LTD	United Kingdom
▶ NB 0041	BUREAU VERITAS UK LIMITED	United Kingdom
▶ NB 0044	TÜV NORD CERT GmbH	Germany
▶ NB 0045	TÜV NORD Systeme GmbH & Co. KG	Germany



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Single Market and Standards - links

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Publications

› NB 0041	BUREAU VERITAS UK LIMITED	United Kingdom
› NB 0044	TÜV NORD CERT GmbH	Germany
› NB 0045	TÜV NORD Systems GmbH & Co. KG	Germany
› NB 0048	DANMARKS GASmateriel PrøVNING	Denmark
› NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
› NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
› NB 0052	CUALICONTROL- ACL, S.A.	Spain
› NB 0053	TÜV SÜD ATISAE, S.A.U.	Spain
› NB 0056	BUREAU VERITAS INSPECCION Y TESTING, S.L. UNIPERSONAL	Spain
› NB 0057	EUROCONTROL S.A.	Spain
› NB 0058	OCA INSPECCION, CONTROL Y PREVENCIÓN, S.A.U.	Spain
› NB 0059	APPLUS NORCONTROL, S.L.U.	Spain
› NB 0060	APAVE	France
› NB 0062	BUREAU VERITAS SERVICES	France
› NB 0063 (ex-0620,0956)	Kiwa Nederland B.V.	Netherlands
› NB 0066	ISTITUTO DI CERTIFICAZIONE EUROPEA PRODOTTI INDUSTRIALI S.P.A.	Italy
› NB 0068	MTIC InterCert S.r.l.	Italy
› NB 0071	Laboratoire National de métrologie et d'Essais (LNE)	France
› NB 0072	Institut Français de Textile et de l'Habillement (IFTH)	France
› NB 0073	INSTITUT DE RADIOPROTECTION ET DE SÛRETÉ NUCLÉAIRE	France
› NB 0074	GINGER CEBTP	France
› NB 0075	CTC	France
› NB 0078	INSTITUT NATIONAL DE LA PLONGÉE PROFESSIONNELLE	France
› NB 0080	INSTITUT NATIONAL DE L'ENVIRONNEMENT INDUSTRIEL ET DES RISQUES	France
› NB 0081	LABORATOIRE CENTRAL DES INDUSTRIES ELECTRIQUES	France
› NB 0082	APAVE SUDEUROPE SAS	France
› NB 0085	DVGW CERT GmbH	Germany
› NB 0086	BSI Assurance UK Ltd	United Kingdom
› NB 0087	GL Industrial Services UK Ltd	United Kingdom
› NB 0088	LLOYD'S REGISTER QUALITY ASSURANCE LTD (0088)	United Kingdom
› NB 0090	TÜV Thüringen e.V.	Germany
› NB 0091	TUV Technische Überwachung Hessen GmbH	Germany
› NB 0094	LLOYD'S REGISTER ESPAÑA, S.A.	Spain
› NB 0096	SGS, TECNOS, S.A.	Spain
› NB 0097	DNV GL UK LIMITED	United Kingdom
› NB 0098	DNV GL SE	Germany
› NB 0099	AENOR INTERNACIONAL, S.A. (Unipersonal)	Spain
› NB 0100	INAIL - DIPARTIMENTO INNOVAZIONI TECNOLOGICHE E SICUREZZA DEGLI IMPIANTI, PRODOTTI ED INSEDIAMENTI ANTROPICI - Sezione Tecnico Scientifica Organismo Notificato per Direttive Europee	Italy







Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

QINGZHOU YAOWANG PHARMACEUTICAL CO., LTD.
No.3787, New York Road, Economy Development Zone Qingzhou,
Shandong, 262515, CHINA
has completed the FDA Establishment Registration (as manufacturer, foreign exporter)
and Device Listing with the US Food & Drug Administration through

U.S. Agent for FDA: SUNGO TECHNICAL SERVICE INC.
6050 W EASTWOOD AVE-APT 201, CHICAGO,
ILLINOIS 60630, USA
Communications: Telephone: +1-855-957-7779 E-mail: sungo.group@yahoo.com

Owner/Operator Number: 10063424
Device Listing#:

Listing No	Code	Device Name
D376321	LYU	ACCESSORY SURGICAL APPAREL (Protective mask, disposable (medical) face mask)
D376323	OEA	Non-surgical isolation gown (Protective Coverall)

SUNGO Technical Service Inc. 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. SUNGO Technical Service Inc. 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. SUNGO Technical Service Inc. 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. SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.



Certificate of Compliance



No. 4L200320T.QYP0U35
Technical Construction file no: 13791680315

Certificate's Holder: Qingzhou Yaowang Pharmaceutical Co., Ltd.
No.3787, New York Road, Economy Development Zone, Qingzhou City, Shandong Province, China

Certification ECM Mark:

Product: Protective face mask
Model(s): N95/FFP3

Verification to: Standard: EN 149:2001+A1:2009
related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

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 according to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



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.3 available at: www.entecema.it

Issuance date: 20 March 2020
Expiry date: 19 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Beronni

Ente Certificazione Macchine Srl
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European Safety Federation

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COVID19

suspicious certificates for PPE - updated 26/05/2020

remark : this article is valid for Personal Protective Equipment (PPE), such as protective masks (type FFP2 or FFP3), protective glasses and face shields, protective gloves and garments, etc. The conformity assessment procedures for medical devices (e.g. medical or surgical masks) are different and for those you should seek information from the relevant trade associations or authorities. The manufacturer must also check of other legislation is simultaneously applicable to the product (e.g. REACH is always applicable).

Given the huge amount of requests, we ask you to first read the complete article, before contacting ESF or one of the national trade associations of PPE suppliers. If you have a 'certificate' for PPE that is clearly not from a Notified Body for PPE (this certainly means all institutes from outside EU, Switzerland or Turkey), there is no doubt that the document is not a valid legal base for CE marking.

Everybody is working very hard and with the best intentions to make the necessary PPE available to the healthcare workers and other people involved in the fight against the COVID-19 crisis.

In first instance the Declaration of Conformity (DoC) has to be provided and checked. For products imported from outside the EU (including EFTA and other participants to the single market), the importer has to make sure that the manufacturer has done the conformity assessment as foreseen in the PPE Regulation (EU) 2016/425. In case where their is doubt about the DoC or there is no DoC available or there is import from outside the EU, it makes sense or is even necessary to check the certification. See the articles "[what to do when importing PPE \(e.g. FFP2 masks\) to the EU ?](#)" and "[conformity assessment procedure for PPE](#)". See also guidance document "[How to verify that medical devices and personal protective equipment can be lawfully placed on the EU market and thus purchased and used - also in the COVID-19 context](#)" published by the EU Commission.

Unfortunately, we (the European Safety Federation (ESF) = trade association of suppliers of PPE, a not for profit organisation funded by the members) are informed by different sources about 'certificates' or other documents used as basis for CE marking of PPE (including FFP2/FFP3 masks and eye protection), while these 'certificates' have no legal value and can not be used as conclusion of conformity assessment. It is not clear if these documents have actually been issued by the organisations mentioned themselves or if they are fake (we have the impression that **a lot of fake documents** are being presented as proof of compliance). ESF is not accusing them of doing so, we only want to inform and warn about these documents.

Several of the mentioned institutes offer the possibility to check the validity of the 'certificate' on their website. In those cases, a 'valid' response does not make the document a legally valid type examination certificate. It only means that the institute recognises that they have issued the 'certificate' to this producer for the mentioned product.

So far we have seen 'certificates' on letterhead (or using their logo and/or name) of the following institutes based in Europe (examples at the bottom of this page) - the institutes are not a notified body competent for PPE mentioned in the document or the documents are fake :

- ICR Polska - see update 31/03/2020, 06/04/2020 and 14/04/2020 below - ICR is not a notified body for PPE (they are for other products)
- CELAB - see statement on their webpage <https://celab.com/en/coronavirus/> - CELAB is not a notified body for PPE (they are for other products)
- ECM (Ente Certificazione Macchine) - also a picture of a mask with identification number of the notified body ECM 1282 next to CE - ECM is not a notified body for PPE (they are for other products), so this marking is certainly not valid - see update 03/04/2020 below.



So far we have seen 'certificates' on letterhead (or using their logo and/or name) of the following institutes based in Europe (examples at the bottom of this page) - the institutes are not a notified body competent for PPE mentioned in the document or the documents are fake :

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- ECM (Ente Certificazione Macchine) - also a picture of a mask with identification number of the notified body ECM 1282 next to CE - ECM is not a notified body for PPE (they are for other products), so this marking is certainly not valid) - see update 03/04/2020 below
- ISET (Istituto Servizi Europei Tecnologici) - on their website they have a page with false certificates - see <http://www.iset-italia.eu/index/service/fal.html> (<http://www.iset-italia.eu/index/service/fal.html>) - ISET is Notified Body for some types of PPE, but not for respiratory protection (masks)
- NPS
- Amtre Veritas
- STS Inspection and Certification
- VIC Testing and Certification
- BSI Test Limited : we have also added an example of a 'certificate of compliance' issued by 'BSI Test Limited, London' which is clearly not issued by the Notified Body for PPE BSI and this is confirmed by the Notified Body BSI - so this one is not a valid EU Type Examination certificate.
- ISP (UK Inspec International) : the document as example is titled 'declaration of conformity' but the text refers to 'certificate'
- NTC (Nationaux de Certification Technique - CHCS)
- Ecole Supérieure du Bois : This institute provided us the example. The name and address of the Ecole Supérieure du Bois in France is used together with the name Euroscene Business Solutions Limited. The Ecole Supérieure du Bois is active in construction products and confirms that they do not issue certificates for PPE. They have no relationship with Euroscene Business Solutions Limited. This is clearly a **fake** document abusing their name.
- Sapo (Sapo Certification & Testing Laboratory Limited)

We have seen **falsified** (type examination) certificates using the name, logo and/or layout of the following Notified Bodies for PPE (examples at the bottom of this page). These are not issued by themselves, so they are a victim of fraude and can not be blamed for this abuse :

- BSI : we have an example of a BSI EU Type Examination Certificate that has clearly been changed and is thus a **fake** document - this is confirmed by the Notified Body for PPE BSI. Certificates of BSI can be verified on <https://verifeyedirectory.bsigroup.com/> (<https://verifeyedirectory.bsigroup.com/>)
- VUBP (Vyzkumny ustav bezpecnosti prace) : we received an example of a 'certificate of conformity' using the name and logo of VUBP. This example has been confirmed by the Notified Body VUBP to be **fake**
- CSI : CSI sent us an example of a fake certificate for masks using their name and NB number. CSI is a notified body for different types of PPE, but not for respiratory protection. There is no doubt that the example is a **fake** document
- Apave Sudeurope : we received an example of an Apave EU Type Examination certificate - this document is not issued by the Notified Body Apave and is confirmed by them to be a **fake** document.
- Centexbel : we received examples from Centexbel of type examination certificates that have been falsified - so confirmed by them to be **fake** documents.



TEST REPORT
EN 149**Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking**

Report Reference No	20ZCTS0317019SP
Checked by (printed name and signature) ... :	Kevin Yang
Approved by (printed name and signature) ... :	King Hu
Date of issue	Mar.20, 2020
Testing laboratory	Shenzhen ZCT Technology Co., Ltd.
Address	3F,5th Building,Bao'an Road 4336, Bao'an District,Shenzhen,China
Applicant's name	Guangzhou Tayhamn Safety Equipment Manufacturing Co., Ltd.
Address	Yonghe Industrial Park, No.1, North Xinsha avenue, Shapu, Xintang town, Zengcheng district, Guangzhou, China
Manufacturer's name	Guangzhou Tayhamn Safety Equipment Manufacturing Co., Ltd.
Address	Yonghe Industrial Park, No.1, North Xinsha avenue, Shapu, Xintang town, Zengcheng district, Guangzhou, China
Factory's name	Same as applicant
Address	
Test specification:	
Standard	EN 149:2001+A1:2009
Test procedure	CE
Non-standard test method	N/A
Test Report Form No	20ZCTS0317019SP
TRF Originator	ZCT
Master TRF	Dated 2019-01
Test item description	TH2210 /TH2210V(with respirator valve) Dust mask
Trade Mark	N/A
Model/Type reference	TH2210 /TH2210V -10cmX15.5 cm-4P
Ratings	--

**Possible test case verdicts:**

- test case does not apply to the test object ... N (Not apply)
- test object does meet the requirement.....P (Pass)
- test object does not meet the requirement....F (Fail)

Testing

Date of receipt of test item Mar.12, 2020

Date(s) of performance of tests Mar.12, 2020 to Mar.20, 2020

General remarks:

The test results presented in this report relate only to the object tested.

This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory

“(See Enclosure #)” refers to additional information appended to the report.

“(See appended table)” refers to a table appended to the report.

General product information:

N/A

Copy of marking plate:

TH2210 /TH2210V(with respirator valve) Dust mask
Model:TH2210 /TH2210V -10cmX15.5 cm-4P
Classification:FFP2 NR
Standard: EN 149:2001+A1:2009

Guangzhou Tayhamn Safety Equipment Manufacturing Co., Ltd.
Made in China




Details of: TH2210 /TH2210V(with respirator valve) Dust mask,
model : TH2210 /TH2210V -10cmX15.5 cm-4P

View:

- [X] general
- [] front
- [] rear
- [] right
- [] left
- [] top
- [] bottom



Øyevern

 **Norsk Standard**
NS-EN 166
2. utgave mars 2002


ICS 13.340.20
Språk: Engelsk

Øyevern
Spesifikasjoner

Personal eye-protection
Specifications

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Provided by standard online as for Oslo+universitetssykehus 2020-06-02

 **Norsk Standard**
NS-EN 168
2. utgave mars 2002

ICS 13.340.20
Språk: Engelsk

Øyevern
Ikke-optiske prøvingsmetoder

Personal eye-protection
Non-optical test methods

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Hvilken kategori er øyevern?

Regulation 2016/425, Annex I: Harmful biological agents: category III



Hvilken kategori er øyevern? - forts

PPE regulation guidelines, April 2018: Category II (?)

PPE Regulation (EU) 2016/425 Guidelines – 1st Edition – April 2018

Type of PPE	Certification category	Reason
2. Equipment for eye protection		
2.1 All eye protectors and filters, including eye protectors against artificial UV radiation (e.g. in sunbeds) and protective glasses for phototherapy on babies	II	3.2.
<i>Except:</i>		
2.2 Eye protectors and filters designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterised by the presence of infra-red radiation, flames, hot splashes or the projection of large amounts of molten materials	III	3.3. (e)
2.3 Eye protectors and filters designed and manufactured to provide protection against ionising radiation	III	3.3. (d)
2.4 Eye protectors and filters designed and manufactured to provide protection against electric shock	III	3.3. (h)
2.5 Swimming and/or diving goggles and masks	I	3.1. (a)
2.6 Eye protectors and filters designed and manufactured exclusively to provide protection against sunlight, sun glasses (not corrective) for private and professional use. This includes cases where glasses are tinted after manufacturing or any other assembly after manufacturing (e.g. assembly of sunlight protective lenses in a non CE marked frame)	I	3.1. (d)
2.7 Ski goggles of all types, except corrective spectacles	I	3.1. (d)
2.8 Corrective spectacles including corrective sunglasses <i>Note: Where corrective spectacles provide protection other than protection against sunlight (e.g. against impact, abrasive projections, etc.), they are classified as personal protective equipment of the category corresponding to the risk in question solely in respect of their protective features</i>	Depends on which risk protection is given against	<i>See also the interpretative document between the PPED and MDD¹³</i>
2.9 Visors incorporated into helmets designed and manufactured for use with two- or three-wheeled motor vehicles	Not PPE	2.5.





*A-Magasinet nr. 21
22. mai 2020*

Feil:
Mangler nummer for
teknisk kontrollorgan.
Ikke korrekt 3. parts
kontroll

Bilder fra Øystein Roll, Sykehusinnkjøp HF



Nasjonal innkjøpsordning av smittevernutstyr

- Helse Sør-Øst RHF fikk i oppdrag av Hdir og HOD om å koordinere nasjonalt innkjøp av smittevernutstyr til både spesialisthelsetjenesten og primærhelsetjenesten i Norge
- Sykehusinnkjøp har ansvar for innkjøpene – avtalene inngås av Helse Sør-Øst
- Spedisjon/frakt av varene til Norge håndteres av HSØ med eget team, innleie av eget fraktfly, samt via tog og båt.
- Nasjonalt felleslager (NFL) etablert på Kløfta – transitlager for videre fordeling til 4 regionale lagre i Norge (HSØ FS)
- Over 90% av volum kommer fra Kina- hansker i hovedsak fra Malaysia. Noe åndedrettsvern fra England og Mexico

Smittevernutstyr som omfattes av ordningen

- Desinfeksjonsmidler (ikke via NFL)
- Hansker (delvis via grossister, beredskap/supplement via NFL)
- Smittevernfrakker
- Vernedresser
- Stellefrakker og plastforklær
- Åndedrettsvern (FFP2, FFP3 og N95)
- Kirurgiske munnbind m/strikk og knyting
- Vernebriller og visir
- Hodebeskyttelse

Sykehusinnkjøp har fått unntak til krav om CE-merking til nasjonal innkjøpsordning fra HDir



Vedtak

Med hjemmel i forskrift 6. mars 2020 nr. 239 om tiltak for å sikre forsyningen av legemidler, medisinsk utstyr og personlig verneutstyr som følge av utbruddet av koronaviruset § 4 første ledd fatter Helsedirektoratet følgende vedtak:

1. For å sikre tilgang til personlig smittevernutstyr til bruk i helse- og omsorgstjenesten, gis det ved anskaffelser foretatt av Sykehusinnkjøp HF unntak fra kravene til markedsføring, anskaffelse og bruk av slike produkter gitt i:
 - a) Forskrift 6. desember 2011 nr. 1355 om organisering, ledelse og medvirkning
 - b) Forskrift 22. juni 2018 nr. 1019 om konstruksjon, utforming og produksjon av personlig verneutstyr (PVU)
 - c) Forskrift 29. november nr. 1373 om håndtering av medisinsk utstyr
 - d) Forskrift 15. desember nr. 1690 om medisinsk utstyr
2. Det forutsettes at sikkerhet for brukere og pasienter er tilfredsstillende ivaretatt og at nærmere retningslinjer for dokumentasjon av kvalitet gitt av Helsedirektoratet følges.
3. Unntaket gjelder kun for smittevernutstyr som skal benyttes i helsetjenesten i forbindelse med koronakrisen. Produktene skal ikke distribueres for bruk utenfor helsetjenesten.

Vedtaket gjelder fram til forskriften oppheves, eller senest fram til 1. januar 2021.

I lite grad benyttet dette unntaket, men gjelder i hovedsak:

- Åndedrettsvern N95 (FDA approved)
- Norskproduserte visir og frakker

Gjelder kun innkjøp gjennom Sykehusinnkjøp og ikke for sykehus og kommuner som kjøper på egenhånd

Kvalitetskontroll i flere ledd

- Innsatsteamet i Sykehusinnkjøp foretar dokumentasjonskontroll av tilbudte varer før avtale inngås –erfarne innkjøpere
- Sjekker dokumentasjon og testrapporter opp mot gjeldende relevante standarder (fra Lingaas)
- Erfarent smittevernpersonell foretar inspeksjon og kvalitetskontroll ved mottak på NFL av alle varer
- Åndedrettsvern og munnbind sendes til FFI for testing mot henholdsvis EN149 og EN14683 standard. Samme produsent testes flere ganger ved ulike forsendelser (annen batch/LOT)

Falske sertifikater

ICR



ICR
International Certification Register - International Certification Register

Certificate

NO. ICR Polska/M600201313 **CE**

Name and address of Certificate owner: Guangzhou Tayhamn Safety Equipment Manufacturing Co., Ltd.
Yonghe Industrial Park, No.1, North Xinsha avenue, Shapu, Xintang town, Zengcheng district, Guangzhou, China

Product name: FACE MASK
Product types: TH2210 /TH2210V /TH6210C /TH6210VC

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425
EN 149:2001+A1:2009

The certification process has been carried out in accordance with the program PC.P07.07. Evaluation has been carried out in accordance with test reports made by Shanghai MICEZ Equipment Testing & Technical Co, LTD Laboratory.

NO. of test reports: MICEZ-20200302PPE

Certificate issue date: March 13, 2020
Expiration date: March 13, 2023

The mutual obligations and rights of the certification are regulated by the contract NO. ICR Polska/2020-0118.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.

ICR
Director: Rafał Kalinowski

Warsaw, 13.03.2020

ICR Polska Co. Ltd.
ul. Plac Przymorza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com

ECM



Form GAT_10-M04, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 4M200323T.GTS0D02
Technical Construction File no. 20ZCTS03170195P

Certificate's Holder: Guangzhou Tayhamn Safety Equipment Manufacturing Co., Ltd.
Yonghe Industrial Park, No.1, North Xinsha avenue, Shapu, Xintang town, Zengcheng district, Guangzhou, China

Certification ECM Mark: 

Product: TH2210 /TH2210V (with respirator valve) Dust mask
Model(s): TH2210 /TH2210V -10cmX15.5 cm-4P

Verification to: Standard: EN149-2001+A1-2009
related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

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 according 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. This document has been issued on the basis of the regulation on ECM voluntary Mark for the certification of products. ISO1_ECM rev.3 available at: www.entecema.it

Issuance date: 23 March 2020
Expiry date: 22 March 2025

Reviewer: Technical expert Amanda Payne
Approver: ECM Service Director Luca Sedgnini

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 - Loc. Castello di Senavalle - 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 ☎ +39 051 6705156 ✉ info@entecema.it 🌐 www.entecema.it

Certificate - Сертификат - 證明書 - 證明書 - 증명서 - 証明書

“Certificate of compliance”. Et slikt dokument kan lett feiltolkes som en gyldig samsvarserklæring (declaration of conformity) og godkjent CE-merking.

Falske sertifikater

European Safety Federation har publisert en nettsak som belyser spørsmålet om falske sertifikater: <https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe>

Av nettsaken fremgår det at verken ICR eller ECM er godkjent for å gi CE-godkjenning til åndedrettsvern, og om ECM heter det følgende: “ECM is not a notified body for PPE (they are for other products), so this marking is certainly not valid”.

Erfaringer

- Kjente leverandører med erfaring på tilsvarende produkter har som regel dokumentasjon i orden
- Mange aktører som ikke kjenner til bransjen/produktene fra tidligere lar seg lure og klarer ikke å vurdere dette
- KN95 masker med ørestrikk kjøpt inn av kommuner og sykehus i stort monn utenfor nasjonal innkjøpsordning testet mot EN149 hos FFI= O godkjente produkter
- N95 masker med FDA godkjenning oppfyller EN149 som regel
- De aller fleste munnbind har vist seg å være godkjent iht. EN14683 type II.

