



REGIONE CAMPANIA
AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE E DI ALTA SPECIALIZZAZIONE
"SANT'ANNA E SAN SEBASTIANO"
CASERTA

Deliberazione del Direttore Generale N. 706 del 02/07/2025

Proponente: Il Direttore UOC PROVVEDITORATO ED ECONOMATO

Oggetto: PROCEDURA APERTA PER LA FORNITURA ANNUALE DI MASCHERINE CHIRURGICHE, FACCIALI FILTRANTI FFP2 E FFP3 (DET. D.G. SO.RE.SA. N. 227-2024) - ADESIONE AZIENDALE

PUBBLICAZIONE

In pubblicazione dal 02/07/2025 e per il periodo prescritto dalla vigente normativa in materia (art.8 D.Lgs 14/2013, n.33 e smi)

ESECUTIVITA'

Atto immediatamente esecutivo

TRASMISSIONE

La trasmissione di copia della presente Deliberazione è effettuata al Collegio Sindacale e ai destinatari indicati nell'atto nelle modalità previste dalla normativa vigente. L'inoltro alle UU. OO. aziendali avverrà in forma digitale ai sensi degli artt. 22 e 45 D.gs. n° 82/2005 e s.m.i. e secondo il regolamento aziendale in materia.

UOC AFFARI GENERALI

Direttore Eduardo Chianese

ELENCO FIRMATARI

Gaetano Gubitosa - DIREZIONE GENERALE

Teresa Capobianco - UOC PROVVEDITORATO ED ECONOMATO

Carmela Zito - UOC GESTIONE ECONOMICO FINANZIARIA

Angela Annecchiarico - DIREZIONE SANITARIA

Amalia Carrara - DIREZIONE AMMINISTRATIVA

Eduardo Chianese - UOC AFFARI GENERALI

Oggetto: PROCEDURA APERTA PER LA FORNITURA ANNUALE DI MASCHERINE CHIRURGICHE, FACCIALI FILTRANTI FFP2 E FFP3 (DET. D.G. SO.RE.SA. N. 227-2024) - ADESIONE AZIENDALE

II DIRETTORE UOC PROVVEDITORATO ED ECONOMATO

A conclusione di specifica istruttoria, descritta nella narrazione che segue e i cui atti sono custoditi presso la struttura proponente, rappresenta che ricorrono le condizioni e i presupposti giuridico-amministrativi per l'adozione del presente provvedimento, ai sensi dell'art. 2 della Legge n. 241/1990 e s.m.i. e, in qualità di responsabile del procedimento, dichiara l'insussistenza del conflitto di interessi, ai sensi dell'art. 6 bis della legge 241/90 e s.m.i.

PREMESSO CHE

la SO.RE.SA. Spa:

- sulla base dei fabbisogni espressi dalle Aziende Sanitarie e Ospedaliere della Regione Campania, ha indetto, con la Determinazione del Direttore Generale n. 71 del 21 marzo 2024, la "Procedura aperta per l'affidamento della fornitura di mascherine chirurgiche, Facciali Filtranti FFP2 e FFP destinate alle AA.SS. della Regione Campania";
- con Determinazione del Direttore Generale n. 227/2024 ha aggiudicato la suddetta procedura di gara;

LETTO l'art. 6 comma 15 della Legge Regionale Campania n.28 del 24.12.2003 così come modificato dalla L.R. n. 5 del 29/05/2021, che stabilisce che "la So.Re.Sa, costituisce Centrale di Committenza Regionale ai sensi dell'art. 3, c.1 ,lett.i) del decreto legislativo 18 aprile 2016, n.50 e Soggetto Aggregatore ai sensi dell'art. 9 del D.L 24 aprile 2014, n. 89, che aggiudica appalti pubblici o conclude accordi quadro di lavori, servizi e forniture destinati alle ASL E AO, alle società partecipate in misura totalitaria dalla Regione Campania, ivi comprese quelle in House, ad eccezione di EAV Srl e di Sviluppo Campania Spa, agli enti anche strumentali della regione, diversi da quelli del trasporto su ferro e su gomma, agli enti locali e alle altre pubbliche amministrazioni aventi sede nel medesimo territorio";

PRESO ATTO CHE con nota Prot. So.Re.Sa.-00016875-2024 del 24/10/2024 (acquisita al Prot. n. 31312/e – agli atti), la predetta Centrale di committenza regionale ha trasmesso un Vademecum con la sintesi di tutte le fasi procedurali previste per l'adesione al succitato Appalto;

DATO ATTO CHE si è proceduto alla compilazione della scheda di adesione concernenti i Lotti nn. 1, 2 e 3 in capo alla Ditta Pizzocri S.r.l. per le quantità già indicate in sede di raccolta fabbisogni (allegato n. 1);

VISTE le comunicazioni inoltrate dalla medesima So.re.sa. Prot. n.10113/2025 (allegato n.2) Prot. n.10832/2025 (allegato n.3) concernenti l'aggiornamento tecnologico, senza alcuna variazione di spesa, autorizzato dalla predetta Centrale di Committenza rispettivamente per i lotti nn.1 e 2 e per il lotto n.3, tutti in capo alla succitata Ditta, come sotto dettagliato:

Lotto n. 1 – Mascherine chirurgiche a 4 strati di tipo IIR – nuovo codice prodotto "XR001";

Lotto n.2 – Mascherine FFP2 NR senza valvola – nuovo codice prodotto "VS005";

Lotto n.3 – Mascherine FFP3 NR senza valvola – nuovo codice prodotto "MV99";

Deliberazione del Direttore Generale

ESAMINATA tutta la documentazione innanzi richiamata, allegata alla presente ed in atti giacente;

RITENUTO di

- procedere a formalizzare l'adesione alla *“Procedura aperta per l'affidamento della fornitura di mascherine chirurgiche, Facciali Filtranti FFP2 e FFP destinati alle AA.SS. della Regione Campania”* (Determina So.Re.Sa. SpA. n. 227/2024) - relativamente ai Lotti nn. 1, 2 e 3 - giusta dettaglio scheda di adesione (già allegato n.1), per un importo complessivo pari ad € 8.960,00 esclusa iva al 5%;
- prendere atto che – relativamente ai lotti nn. 1 – 2 e 3, presenti nell'adesione in parola, la medesima Soresa ha autorizzato l'aggiornamento tecnologico, senza alcuna variazione di spesa, come esplicitato in narrativa e qui integralmente trascritto;

ATTESTATA la legittimità della presente proposta di deliberazione, che è conforme alla vigente normativa in materia

PROPONE

I - DI PROCEDERE a formalizzare l'adesione alla *“Procedura aperta per l'affidamento della fornitura di mascherine chirurgiche, Facciali Filtranti FFP2 e FFP destinati alle AA.SS. della Regione Campania”* (Determina So.Re.Sa. SpA. n. 227/2024) - relativamente ai Lotti nn. 1, 2 e 3 - giusta dettaglio scheda di adesione (già allegato n. 1), per un importo complessivo pari ad € 8.960,00 esclusa iva al 5%;

II – DI PRENDERE ATTO CHE – relativamente ai lotti nn. 1 – 2 e 3, presenti nell'adesione in parola, la medesima Soresa ha autorizzato l'aggiornamento tecnologico, senza alcuna variazione di spesa, come esplicitato in narrativa e qui integralmente trascritto;

III - DI IMPUTARE la spesa complessiva, di € 9.408,00 incluso Iva al 5% al conto economico 5010107010 “Dispositivi Medici” come di seguito riportato:

- € 4.704,00 corrispondente a 06/12 della fornitura al bilancio 2025;
- € 4.704,00 corrispondente a 06/12 della fornitura al bilancio 2026;

IV - DI INDIVIDUARE quale RUP il Direttore UOC Provveditorato Dr.ssa Teresa Capobianco e DEC il Responsabile della UOS Economato e Patrimonio;

V - DI NOTIFICARE copia del presente provvedimento alla Ditta Pizzocri Srl.;

VI - DI TRASMETTERE copia del presente atto al Collegio Sindacale, come per legge, alle U.O.C. Gestione Risorse Economico-Finanziarie ed alla So.re.sa. Spa.;

VII - DI DICHIARARE la presente immediatamente eseguibile, stante l'urgenza di trasmettere l'atto di adesione a SO.RE.SA. S.p.A.

Il funzionario

Dott.ssa Antonella De Icco

IL DIRETTORE
U.O.C. PROVVEDITORATO ED ECONOMATO
Dott.ssa Teresa Capobianco

Deliberazione del Direttore Generale

IL DIRETTORE GENERALE

Dr. Gaetano Gubitosa

individuato con D.G.R.C. n. 465 del 27/07/2023

impresso nelle funzioni con D.P.G.R.C. n. 80 del 31/07/2023

Vista la proposta di deliberazione che precede, a firma del Direttore UOC Provveditorato ed Economato Dott.ssa Teresa Capobianco

Acquisiti i pareri favorevoli del Direttore Sanitario e del Direttore Amministrativo in modalità telematica (art. 6, punto 1, lett e del regolamento aziendale) e sotto riportati

Il Direttore Sanitario	Dr.ssa Angela Annetichiarico	favorevole
Il Direttore Amministrativo	Avv. Amalia Carrara	favorevole

DELIBERA

per le causali in premessa, che qui si intendono integralmente richiamate e trascritte, di prendere atto della proposta di deliberazione che precede e, per l'effetto, di:

I - PROCEDERE a formalizzare l'adesione alla "Procedura aperta per l'affidamento della fornitura di mascherine chirurgiche, Facciali Filtranti FFP2 e FFP destinati alle AA.SS. della Regione Campania" (Determina So.Re.Sa. SpA. n. 227/2024) - relativamente ai Lotti nn. 1, 2 e 3 - giusta dettaglio scheda di adesione (già allegato n. 1), per un importo complessivo pari ad € 8.960,00 esclusa iva al 5%;

II - DI PRENDERE ATTO CHE - relativamente ai lotti nn. 1 - 2 e 3, presenti nell'adesione in parola, la medesima Soresa ha autorizzato l'aggiornamento tecnologico, senza alcuna variazione di spesa, come esplicitato in narrativa e qui integralmente trascritto;

III - DI IMPUTARE la spesa complessiva, di € 9.408,00 incluso Iva al 5% al conto economico 5010107010 "Dispositivi Medici" come di seguito riportato:

- € 4.704,00 corrispondente a 06/12 della fornitura al bilancio 2025;
- € 4.704,00 corrispondente a 06/12 della fornitura al bilancio 2026;

IV - DI INDIVIDUARE quale RUP il Direttore UOC Provveditorato Dr.ssa Teresa Capobianco e DEC il Responsabile della UOS Economato e Patrimonio;

V - DI NOTIFICARE copia del presente provvedimento alla Ditta Pizzocri Srl.;

VI - DI TRASMETTERE copia del presente atto al Collegio Sindacale, come per legge, alle U.O.C. Gestione Risorse Economico-Finanziarie ed alla Soresa Spa.;

VII - DI DICHIARARE la presente immediatamente eseguibile, stante l'urgenza di trasmettere l'atto di adesione a SO.RE.SA. S.p.A.

Il Direttore Generale
Gaetano Gubitosa

Deliberazione del Direttore Generale



REGIONE CAMPANIA
AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE E DI ALTA SPECIALIZZAZIONE
"SANT'ANNA E SAN SEBASTIANO"
CASERTA

ATTESTAZIONE DI VERIFICA E REGISTRAZIONE CONTABILE
(per le proposte che determinano un costo per l'AORN – VEDI ALLEGATO)

Deliberazione del Direttore Generale

Il presente atto, in formato digitale e firmato elettronicamente, costituisce informazione primaria ed originale ai sensi dei combinati disposti degli artt. 23-ter, 24 e 40 del D.Lgs. n. 82/2005. Eventuale riproduzione analogica, costituisce valore di copia semplice a scopo illustrativo.

Prospetto di sintesi delle Adesioni per Fornitore e per Lotto

13/02/2025

File 1

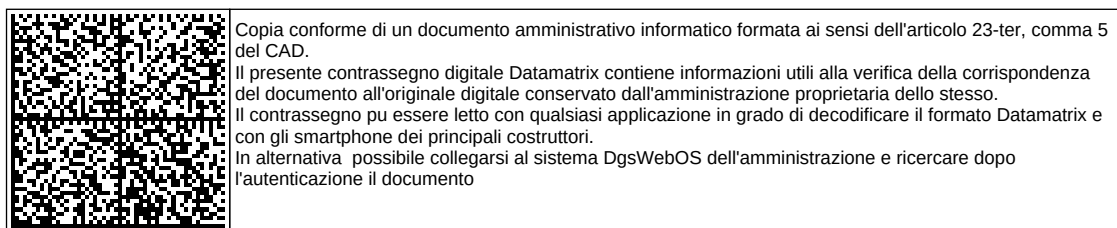
SINTESI DELLE ADESIONI

Desc. Aggiudicatario	Lotto	Descrizione Prodotto	Somma di Quantità		Somma di Valore	
PIZZOCRI SRL	1	Mascherine chirurgiche - MASCHERINA CHIRURGICA IIR TYPE A 4 STRATI MC	150000	€	2.100,0000	
	2	Filtranti facciali FFP2 senza valvola - FACCIALI FILTRANTI FFP2 NR SENZA	180000	€	6.120,0000	
	3	Filtranti facciali FFP3 senza valvola - MASCHERINA FFP3 NR SENZA VALVOL	10000	€	740,0000	
Totale complessivo			340000	€	8.960,0000	

L' art. 23 del Codice dell'Amministrazione Digitale (Decreto Legislativo 7 marzo 2005, n. 82 e s.m.i.), riconosce alle copie analogiche di documenti informatici (es. la stampa di un certificato, un contratto, ecc.) la stessa efficacia probatoria dell'originale informatico da cui sono tratti se la loro conformità non viene espressamente disconosciuta (in giudizio). Diverso il caso in cui la conformità all'originale informatico, in tutte le sue componenti, sia attestata da un pubblico ufficiale autorizzato. In questo caso, infatti, per negare alla copia analogica di documento informatico la stessa efficacia probatoria del documento sorgente si rende necessaria la querela di falso.

Questo regime, di carattere generale, incontra alcune deroghe rispetto alle copie analogiche di documenti amministrativi informatici.

L'art. 23-ter del CAD prevede che sulle copie analogiche di documenti amministrativi informatici possa essere apposto un contrassegno a stampa (detto anche timbro digitale o glifo) che consente di accertare la corrispondenza tra le copie analogiche stesse e l'originale informatico (in esso deve essere codificato, infatti, il documento informatico o le informazioni necessarie a verificarne la corrispondenza all'originale in formato digitale). La verifica avviene grazie ad appositi software che leggono le informazioni contenute nel timbro digitale. I software necessari per l'attività di verifica devono essere gratuiti e messi liberamente a disposizione da parte delle amministrazioni.



Impronta del documento digitale originale: 42b78a0ab2495efe5f0d17fba2b5727b

Identificativo del documento digitale originale: 648184

Protocollo: SoReSa-0010113-2025 26-05-2025 10:51:18

Ai Sig.ri Direttori Generali
Ai Sig.ri Provveditori
AA.SS.LL., AA.OO., AA.OO.UU., IRCSS
a mezzo pec

e p.c.
Pizzocri S.r.l.
A mezzo pec: pizzocri@pec.sm

Oggetto: Autorizzazione ex art. 19 Convenzione Rep. 80-2024. PROCEDURA APERTA PER L’AFFIDAMENTO DELLA FORNITURA DI MASCHERINE CHIRURGICHE, FACCIALI FILTRANTI FFP2 E FFP3 DESTINATI ALLE AA.SS. DELLA REGIONE CAMPANIA- lotti 1 e 2

Con riferimento alla fornitura in oggetto
vista la richiesta di autorizzazione ex art. 19 della Convenzione presentata dalla società Pizzocri S.r.l. ed acquisita al protocollo interno con n. SoReSa-0008653-2025 del 02/05/2025.

alla luce dell’istruttoria espletata ed acquisito il parere tecnico favorevole circa l’aggiornamento tecnologico proposto dalla Ditta
si autorizza, secondo le previsioni del Capitolato Tecnico di gara, alle medesime condizioni economiche contrattuali, la variazione dei prodotti come da richiesta che costituisce parte integrante e sostanziale della presente e come di seguito indicato:

LOTTO 1 - MASCHERINE CHIRURGICHE A 4 STRATI DI TIPO IIR – NUOVO CODICE PRODOTTO XR001

LOTTO 2 - MASCHERINE FFP2 NR SENZA VALVOLA - NUOVO CODICE PRODOTTO VS005

In allegato:

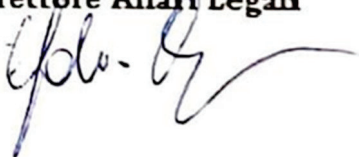
- Istanza di autorizzazione.
- Documentazione tecnica.

Distinti saluti.

So.Re.Sa. S.p.A.
Il Responsabile per l'esecuzione dei contratti
Avv. Gianmarco Massa



Avv. Fabio Aprea
Direttore Affari Legali



Segreteria So.Re.Sa SpA

Da: arealegale@pec.soresa.it
Inviato: venerdì 2 maggio 2025 11:30
A: Segreteria So.Re.Sa SpA
Oggetto: I: RICHIESTA VARIAZIONE CODICE PRODOTTO - CONVENZIONE N. 00000717
FORNITURA DI MASCHERINE CHIRURGICHE, FACCIALI FILTRANTI FFP2 E FFP3
DESTINATI ALLE AA.SS. DELLA REGIONE CAMPANIA
Allegati: PLICO TECNICO FFP2 - VS005 - ITA.pdf; PLICO TECNICO MASCHERINE MYS FFP3
NR- IT.pdf; PLICO TECNICO CHIRURGICHE COMPLETO 4 STRATI IIR XR001 - IT.pdf
Priorità: Alta



Direzione Affari Legali
Centro Direzionale Isola G3
80143 - Napoli
Tel 081.2128174
Fax 0817500012

Da: pizzocri@pec.sm <pizzocri@pec.sm>
Inviato: venerdì 2 maggio 2025 11:29
A: arealegale <arealegale@pec.soresa.it>
Cc: acquisizione.beni <acquisizione.beni@pec.aslna1centro.it>
Oggetto: RICHIESTA VARIAZIONE CODICE PRODOTTO - CONVENZIONE N. 00000717 FORNITURA DI MASCHERINE
CHIRURGICHE, FACCIALI FILTRANTI FFP2 E FFP3 DESTINATI ALLE AA.SS. DELLA REGIONE CAMPANIA
Priorità: Alta

Buongiorno,
con la presente siamo a richiedere la variazione dei codici prodotto della fornitura della convenzione in oggetto, in quanto come precedentemente comunicato i modelli offerti in fase di gara attualmente sono fuori produzione. Vorremmo precisare che le caratteristiche tecniche dei prodotti sostitutivi rispettano il capitolato tecnico al 100%. Colgo l'occasione per allegare la documentazione tecnica dei nuovi prodotti. La variazione del codice prodotto è la seguente:

- **LOTTO 1 - MASCHERINE CHIRURGICHE A 4 STRATI DI TIPO IIR - NUOVO CODICE PRODOTTO XR001**
- **LOTTO 2 - MASCHERINE FFP2 NR SENZA VALVOLA - NUOVO CODICE PRODOTTO VS005**
- **LOTTO 3 - MASCHERINE FFP3 NR SENZA VALVOLA - NUOVO CODICE PRODOTTO MV99**

Restiamo in attesa di ricevere un gentile riscontro, per poter procedere con l'evasione degli ordini ricevuti da ASL NAPOLI 1 CENTRO che ci legge in copia.

A disposizione per qualsiasi altra informazione, saluto cordialmente.

Pizzocri S.r.l.

Via Fondo Ausa, 28 – Dogana (RSM) 47890

C.O.E. 29433 – N° iscr. 8747

C.F. PZZNCL94M04I577V – Tel. 0549/910442

Tel. +39 348/8645908 – pizzocri@pec.sm

Fax: 02/26411996 – Codice ISS 181537

MASCHERINE FFP2 NR SENZA VALVOLA CON ELASTICI AURICOLARI CERTIFICATI COME DPI DI III CATEGORIA

Firmato digitalmente da: NICOLO' PIZZOCRI
Luogo: San Marino
Data: 02/05/2025 11:02:25



Fabbricante:

Mask Authority sp. z o.o.

ul. Targowa 4, 52-326 Wrocław, Poland



Distributore:

Pizzocri S.r.l.

Via Fondo Ausa, 28 – 47891
San Marino (RSM)

www.pizzocri.com info@pizzocri.com

DATI PRINCIPALI DEL PRODOTTO



MATERIALE	TNT 100% Latex Free
MARCA	VIRSHIELDS
COLORE	BIANCO
MODELLO	VS005
FABBRICANTE	Mask Authority sp. Z o.o.
RAPPRESENTANTE EUROPEO	MNA LABORATUVARLARI SANAYI TICARET LIMITED ŞİRKETİ
CND	T0399
RDM	2675688
DPI	III CATEGORIA
DATA PRODUZIONE DEL PRODOTTO	16/09/2021
DATA DI SCADENZA DEL PRODOTTO	16/09/2026

UTILIZZO DEL PRODOTTO E CAMPO DI APPLICAZIONE

Le maschere FFP2 sono una categoria di maschere facciali filtranti che offrono un alto livello di protezione respiratoria. Sono progettate per filtrare particelle sottili, aerosol e sostanze nocive presenti nell'aria, garantendo una maggiore protezione rispetto alle maschere chirurgiche.

Le principali caratteristiche e usi delle maschere FFP2 includono:

- **Protezione da particelle sottili:** Le maschere FFP2 sono progettate per filtrare almeno il 94% delle particelle in sospensione nell'aria, inclusi aerosol, polveri sottili, fumi e nebbie.
- **Ambienti ad alto rischio:** Le maschere FFP2 sono spesso utilizzate in ambienti in cui è presente un rischio elevato di esposizione a sostanze pericolose come agenti patogeni, polveri tossiche, amianto, fumi di saldatura e altre particelle fini nocive.
- **Settori industriali:** Sono ampiamente utilizzate nell'industria chimica, nelle lavorazioni di metalli, nell'edilizia, nell'industria farmaceutica e in altre situazioni lavorative dove la salute dei lavoratori può essere minacciata da sostanze dannose in sospensione nell'aria.
- **Procedure mediche avanzate:** In alcune situazioni mediche, come l'esecuzione di procedure invasive o trattamenti su pazienti con malattie altamente contagiose, le maschere FFP2 possono essere impiegate per proteggere gli operatori sanitari.
- **Protezione individuale:** Le persone con sistemi immunitari compromessi o condizioni mediche che le rendono particolarmente suscettibili alle infezioni potrebbero utilizzare maschere FFP2 per una protezione aggiuntiva quando sono esposte a ambienti con potenziali patogeni.
- **Emergenze ambientali:** In caso di emergenze ambientali, come incendi, eruzioni vulcaniche o altre situazioni in cui l'aria è contaminata da sostanze tossiche, le maschere FFP2 possono essere utilizzate per aiutare le persone a respirare in modo sicuro.

CARATTERISTICHE SPECIFICHE DEL PRODOTTO

- | | |
|---|--|
| <ul style="list-style-type: none">• Facciale filtrante FFP2 con certificazione DPI di III categoria• Marcature CE• Marcatura a norma EN 149-2001 + A1:2009• Maschera filtrante per rischi biologici• Taglia Unica• Senza valvola di esalazione• Imbustate singolarmente• con filtrazione di tipo meccanico• dotate di cerotto ipoallergenico sotto il ferretto stringinaso• materiale di fabbricazione privo di lattice• stringinaso regolabile• elastici fissati al corpo maschera senza uso di graffette metalliche• adatta a tutti i tipi di viso• protezione del mento, naso e bocca• ergonomica, adatta a tutti i tipi di viso | <ul style="list-style-type: none">• mascherine monouso non riutilizzabile, durevole per tutto il turno di lavoro• prodotto biocompatibile• realizzata in materiale resistente ed anallergico• design che permette una perfetta aderenza al viso• efficienza di filtraggio: velocità di filtrazione del particolato non oleoso $\geq 94\%$• confortevole da indossare• protegge dalle particelle dannose per la salute allo stato solido;• idonee a coprire il naso, la bocca ed il mento.• mascherine adatto all'uso in ambito sanitario;• ipoallergenica• confortevole da indossare• alta efficienza• imbustate singolarmente in modo da permettere l'estrazione del singolo dispositivo per volta, nel rispetto delle norme di igiene |
|---|--|

CERTIFICAZIONI E TEST REPORT

CERTIFICATO CE	Modulo B: CE rilasciato il 22/08/2022 da Ciop Pib, Notified Body n. 1437 Certificato n. UE/540/2021/1437 conforme alla direttiva europea 2016/425
	Modulo C2: CE rilasciato il 22/08/2022 da Ciop Pib, Notified Body n. 1437 Certificato n. C2/44/2021/1437 conforme alla direttiva europea 2016/425
DICHIARAZIONE DI CONFORMITA' SECONDO LA NORMATIVA EUROPEA EU 425/2016	A CURA DEL PRODUTTORE
TEST DI LABORATORIO CHE ATTESTA LA CONFORMITA' ALLA NORMATIVA EUROPEA EN 149:2001 + A1:2009	n. 621/PB-COV/2021/NO

CONFEZIONAMENTO

Confezionamento (1° Livello)	1 (una) mascherina in una bustina sigillata di plastica
Confezionamento (2° Livello)	10 (dieci) bustine sigillate di plastica (10 mascherine) in una scatola di cartone
Confezionamento (3° Livello)	45 (quarantacinque) scatole (450 mascherine) in un cartone robusto
Dimensioni e Peso del Catone	60*42*42 cm / 5,00kg

Ogni confezione riporta tutte le informazioni previste dalla normativa vigente e quelle necessarie a garantire una utilizzazione corretta e sicura del dispositivo. Gli imballaggi esterni sono di materiale resistente, tali da poter essere impilati e riportano il tipo, la quantità, la scadenza e il codice del prodotto. Imballo e confezioni sono “a perdere”. Ogni singola scatola ed ogni singola busta esterna riportano i dati previsti dalla Direttiva 2007/46/CE, D.Lgs. 25 gennaio 2010, n. 37. Sulla confezione è riportata la destinazione d'uso. I dispositivi sono contenuti in confezioni che ne garantiscano la corretta conservazione ed il facile immagazzinamento per sovrapposizione. Le singole confezioni sono imballate in scatoloni robusti e a tenuta di polvere. Il materiale di confezionamento è resistente e tale da garantire la corretta conservazione del prodotto.

Tutte le singole confezioni e imballi di spedizione sono provvisti di etichette indelebili che riportano, in lingua italiana, tutte le iscrizioni previste dalla normativa vigente.

Sulla confezione sono riportate, in lingua italiana, tutte le informazioni previste dalla normativa vigente e necessarie per garantire una utilizzazione corretta e sicura del prodotto.

**EU Konformitätserklärung**
EU Declaration of Conformity

Wir, als Hersteller
We, as Manufacturer

MASK AUTHORITY Sp. z o.o.
ul. Targowa 4
52-326 WROCLAW
POLAND

erklären in alleiniger Verantwortung, dass das
declare under our sole responsibility that the product

Partikelfiltrierende Halbmaske
**VS005 FFP2 NR (Farben: weiß, rot, grün, blau
und schwarz)**
Particle filtering half mask
**VS005 FFP2 NR (Colors: white, red, green, blue
and black)**

mit der EU-Baumusterprüfbescheinigung
is in conformity with the EU-Type Examination Certificate

UE / 540 / 2021 / 1437, edition 2

Ausgestellt von der notifizierten Stelle mit der Kenn-Nr.
Issued by the Notified Body with Identification No.

CENTRALNY INSTYTUT OCHRONY PRACY - PANSTWOWY INSTYTUT
BADAWCZY (CIOP-PIB) – No. 1437
ul. Czerniakowska 16
00-701 WARSZAWA

Und mit der folgenden Harmonisierungsrechtsvorschrift der Union unter Anwendung der aufgeführten Norm übereinstimmt:
and is in compliance with the following Union harmonization legislation by application of the listed standard

Bestimmungen der Verordnung
provisions of regulation

Nummer sowie Ausgabedatum der Norm
Number and date of issue of standard

Verordnung (EU) 2016/425

EN 149:2001 +A 1:2009

über persönliche Schutzausrüstungen

Personal Protective Equipment Regulation

☒

**Das Konformitätsbewertungsverfahren nach Modul B, das die
Erfüllung der grundlegenden Gesundheits- und
Sicherheitsanforderungen an persönliche Schutzausrüstungen
gemäß Verordnung Nr. 2016/425 bestätigt**

CENTRALNY INSTYTUT OCHRONY PRACY - PANSTWOWY INSTYTUT
BADAWCZY (CIOP-PIB) – No. 1437
ul. Czerniakowska 16
00-701 WARSZAWA

The conformity assessment procedure according to module B,
confirming the fulfillment of the essential health and safety
requirements of personal protective equipment according to
Regulation No. 2016/425

697/PB-COV/2021/NO, dated 11.10.2021
621/PB-COV/2021/NO, dated 11.10.2021
72/CR-COV/2021/NO, dated 01.02.2021
08/2020, dated 22.12.2020

☒

**Überwachung der Konformität mit der Bauart auf der Grundlage
einer internen Fertigungskontrolle mit überwachten
Produktprüfungen in unregelmäßigen Abständen (Modul C2).**

Surveillance of conformity to type based on internal production control
plus supervised product checks at random intervals
(Module C2).

16.11.2021

Datum / Unterschrift

Date / Signature

Prezes Zarządu
Mask Authority Sp. z o.o.

Robert Zachar

Robert Zachar
Geschäftsführer / Chairman of the Board MASK AUTHORITY Sp. z o.o.

Certificate

of EU type-examination No. UE/540/2021/1437, edition 4

Name of the product:

Filtering half mask

Type (varieties):

VS005 FFP2 NR

Name and address of the manufacturer:

*Mask Authority Sp. z o.o.
Targowa 4
52-326 Wrocław
Poland*

***The product meets the applicable essential health and safety requirements
included in Regulation (EU) 2016/425 of the European Parliament and of the Council
of 9 March 2016***

Validity period: from 22 August 2022 to 7 February 2026

Head of the Centre
for Certification of Personal
Protective and Working Equipment
A. Stefko
Agnieszka Stefko M.Sc.(Eng.)

.....
signature of the certificate issuer's representative

Warsaw, date 22 August 2022

page 1 of 3

Product description:

The filtering half mask type VS005 FFP2 NR without the exhalation valve is a one-way half mask in which the air flows through the filtering material during the inhalation and the exhalation phase. It is a complete device designed for respiratory protection against solid and liquid aerosols.

The filtering part of half mask consists of the following layers of nonwovens:

- the outer layer consisting of the spun-bond nonwoven of the surface mass of 50 g/m^2 ,
- the middle layer consisting of three nonwovens:
 - nonwoven melt-blown of the surface mass of $20 \div 30 \text{ g/m}^2$,
 - nonwoven Hot Air Cotton of the surface mass of 50 g/m^2 ,
 - nonwoven melt-blown of the surface mass of $20 \div 30 \text{ g/m}^2$,
- the inner layer consisting of spun-bond nonwoven of the surface mass of $25 \div 30 \text{ g/m}^2$.

The filtering half mask is equipped with:

- two loops earn made of white rubber or black rubber for black filtering half mask,
- the nose clip made of double wire placed inside the bowl.

The filtering half mask is available in five colors: white, red, green, blue and black.

Image:



Basic parameters:

class, personal protective equipment category, performance level(s) or protection class of the product

- penetration of sodium chloride aerosol - protection class FFP2 NR
- penetration of paraffin oil mist aerosol - protection class FFP2 NR
- breathing resistance - protection class FFP2
- total inward leakage - protection class FFP2
- limited to single shift use only - NR

Identification of the submitted documentation:

- application for EU type-examination No. 71/2021 dated 20.06.2022
- agreement on EU type-examination and review of the EU type-examination certificate No.191/2020/1437, dated 31.12.2020
- technical documentation of filtering half mask: the Filtering half mask VS005 FFP2 NR, Edition 04 dated 17.05.2022
- user's instruction dated 09.03.2022
- manufacturer's declaration on the method of assigning LOT number dated 18.08.2022
- declaration on the harmlessness of the materials used dated 18.08.2022

Product/product model supplied with the EU type-examination application is compliant with the technical documentation.

The product meets the requirements of harmonised standard/technical specifications:

EN 149:2001+A1:2009 "Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking"

confirmed by tests performed by:

1. ProBa Sp. z o.o., Laboratory of Respiratory Protective Devices, Lodz, Poland
2. CIOP-PIB, Department of Personal Protective Equipment, Lodz, Poland

report No.:

1. 08/2020 dated 22.12.2020
2. 72/CR-COV/2021/NO dated 01.02.2021, 621/PB-COV/2021/NO dated 11.10.2021, 697/PB-COV/2021/NO dated 11.10.2021, 807/PB-COV/2021/NO dated 08.10.2021, 813/PB-COV/2021/NO dated 19.11.2021, 814/PB-COV/2021/NO dated 08.10.2021, 823/PB-COV/2021/NO dated 25.10.2021, 223/PB-COV/2022/NO dated 16.05.2022

Marking:

name and address of the manufacturer: Mask Authority Sp. z o.o.; product identification type: VS005; protection symbol: FFP2 NR; standard: EN 149:2001+A1:2009; LOT – the serial number identifying the types of layers in the set of nonwovens/date of manufacture (year/week number); expiration date (year/month); exchangeable logotype identifying the product brand, for example: "virshields®"

The certificate applies in conjunction with one of procedures of conformity assessment according to C2 module or D module pursuant to Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016

NOTE 1:

Every modification to the product and its technical documentation to which this certificate pertains should be notified to the Centre for Certification of Personal Protective and Working Equipment of the Central Institute for Labour Protection – National Research Institute.

This certificate shall be valid as long as the above harmonised standard may be applied as a basis for product examination.

NOTE 2:

Forging the content and the markings of the certificate or modifying them (including a photocopy or scan), or using such document as authentic is a crime under Article 270 § 1 of the Criminal Code.

DEPARTMENT OF PERSONAL PROTECTIVE EQUIPMENT
LABORATORY OF RESPIRATORY PROTECTIVE DEVICES

TEST REPORT

No. 2

Contract to perform testing No.: 621/PB-COV/2021/NO

Subject of the contract: Tests of filtering half masks type:
VS005 FFP2 NR product code:
S27M11H4S28

Ordering Party: MASK AUTHORITY Sp. z o. o.
52-326 Wrocław
Segro Business Park Wrocław, Hala 2
ul. Targowa 4
Poland

Date of issuing the test report: 11-10-2021

Main performer:

Renata Głodek

Authorized by:

KIEROWNIK
ZAKŁADU OCHRONY OSOBISTYCH

dr hab. inż. Katarzyna Majchrzycka
prof. nadzw. CIOP-PIB

Approved by:

HEAD OF TESTING AND
CALIBRATION LABORATORIES
DIVISION

Karolina Burza, MA

Copy No.: 1
Page 1 of 6

Test report No. 2 for the contract to perform testing No. 621/PB-COV/2021/NO replaces the test report for the contract to perform testing No. 621/PB-COV/2021/NO issued on July 26, 2021. Test report No. 2 for the contract to perform testing No. 621/PB-COV/2021/NO was issued at the client's request. The product code S27M11H4S28 was added to the test object description on each page of the report.

Test object:

Nine filtering half masks type VS005 FFP2 NR; product code: S27M11H4S28 were tested. Test object is shown in figure 1. The filtering half masks were delivered by MASK AUTHORITY Sp. z o. o.; 52-326 Wrocław; Segro Business Park Wrocław, Hala 2; ul. Targowa 4, Poland.



*Fig. 1. Filtering half mask model VS005 FFP2 NR; product code: S27M11H4S28
(MASK AUTHORITY Sp. z o. o.).*

Place of testing:	Department of Personal Protective Equipment CIOP-PIB Laboratory of Respiratory Protective Devices Wierzbowa 48, 90-133 Łódź, Poland
Samples registry number:	NO1/89/2021
Samples receiving date:	15.07.2021
Date of completing the tests:	19.07.2021 – 22.07.2021

Identification of test methods:

Breathing resistance: method and requirements in accordance with EN 149:2001+A1:2009

Before tests according to requirements of the standard, filtering half masks were submitted to:

- mechanical strength test according to 8.3.3 of EN 149:2001+A1:2009,
- temperature conditioning according to 8.3.2 of EN 149:2001+A1:2009,
- simulated wearing treatment according to 8.3.1 of EN 149:2001+A1:2009.

Note:

This test report consists of six (6) pages.

This test report may not be copied fragmentarily, but only as the whole unless there is CIOP-PIB permission.

TEST RESULTS OF INHALATION RESISTANCE according to EN 149:2001+ A1:2009

Test object: filtering half masks model VS005 FFP2 NR; product code: S27M11H4S28

No. of sample	Inhalation resistance, Pa						Estimation of conformity / nonconformity with the standard ¹
	Flow rate 0.5 dm ³ s ⁻¹		Requirements in accordance with EN 149:2001 + A1:2009 (tolerance limit - TW)	Flow rate 1.6 dm ³ s ⁻¹		Requirements in accordance with EN 149:2001 + A1:2009 (tolerance limit - TW)	
	Measured value	Uncertainty (U95)		Measured value	Uncertainty (U95)		
08 AR	45	2	FFP1 ≤ 60 Pa FFP2 ≤ 70 Pa FFP3 ≤ 100 Pa	163	6	FFP1 ≤ 210 Pa FFP2 ≤ 240 Pa FFP3 ≤ 300 Pa	Filtering half masks fulfill requirements given in p. 7.16 of the EN 149:2001 + A1:2009 standard for inhalation resistance in the range of the first, the second and the third protection class (FFP1, FFP2, FFP3).
09 AR	47	2		162	6		
10 AR	46	2		165	6		
01 TC	44	2		155	6		
02 TC	46	2		160	6		
03 TC	44	2		158	6		
05 SW	47	2		164	6		
06 SW	48	2		166	6		
07 SW	45	2		165	6		
Given results relate to delivered samples only.							

AR – sample as received

TC – sample after temperature conditioning

SW – sample after the simulated wearing treatment

¹⁾ Estimation of conformity/nonconformity was assessed based on binary statement with guard band; acceptance level (AL) = tolerance limit (TW) – guard band (w); w is equal to expanded uncertainty (U95). Risk of incorrect acceptance ≤2.5%.

TEST RESULTS OF EXHALATION RESISTANCE according to EN 149:2001+ A1:2009

Test object: filtering half masks model VS005 FFP2 NR; product code: S27M11H4S28

No. of sample	The dummy head positions	Exhalation resistance, Pa (flow rate 2.7 dm ³ s ⁻¹)		Requirements in accordance with EN 149:2001 + A1:2009 (tolerance limit - TW)	Estimation of conformity / nonconformity with the standard ¹
		Measured value	Uncertainty (U95)		
08 AR	Facing directly ahead	233	9	FFP1 ≤ 300 Pa FFP2 ≤ 300 Pa FFP3 ≤ 300 Pa	Filtering half masks fulfill requirements given in p. 7.16 of the EN 149:2001 + A1:2009 standard for exhalation resistance in the range of the first, the second and the third protection class (FFP1, FFP2, FFP3).
	Facing vertically upwards	232	9		
	Facing vertically downwards	231	9		
	Lying on the right side	231	9		
	Lying on the left side	235	9		
09 AR	Facing directly ahead	241	9		
	Facing vertically upwards	240	9		
	Facing vertically downwards	239	9		
	Lying on the right side	235	9		
	Lying on the left side	237	9		
10 AR	Facing directly ahead	231	9		
	Facing vertically upwards	240	9		
	Facing vertically downwards	236	9		
	Lying on the right side	238	9		
	Lying on the left side	237	9		

Given results relate to delivered samples only.

AR – sample as received

¹) Estimation of conformity/nonconformity was assessed based on binary statement with guard band; acceptance level (AL) = tolerance limit (TW) – guard band (w); w is equal to expanded uncertainty (U95). Risk of incorrect acceptance ≤2.5%.

TEST RESULTS OF EXHALATION RESISTANCE according to EN 149:2001+ A1:2009

Test object: filtering half masks model VS005 FFP2 NR; product code: S27M11H4S28

No. of sample	The dummy head positions	Exhalation resistance, Pa (flow rate 2.7 dm ³ s ⁻¹)		Requirements in accordance with EN 149:2001 + A1:2009 (tolerance limit - TW)	Estimation of conformity / nonconformity with the standard ¹
		Measured value	Uncertainty (U95)		
01 TC	Facing directly ahead	230	9	Filtering half masks fulfill requirements given in p. 7.16 of the EN 149:2001 + A1:2009 standard for exhalation resistance in the range of the first, the second and the third protection class (FFP1, FFP2, FFP3). FFP1 ≤ 300 Pa FFP2 ≤ 300 Pa FFP3 ≤ 300 Pa	
	Facing vertically upwards	228	8		
	Facing vertically downwards	231	9		
	Lying on the right side	229	9		
	Lying on the left side	225	8		
02 TC	Facing directly ahead	225	8		
	Facing vertically upwards	226	8		
	Facing vertically downwards	223	8		
	Lying on the right side	222	8		
	Lying on the left side	220	8		
03 TC	Facing directly ahead	220	8		
	Facing vertically upwards	227	8		
	Facing vertically downwards	222	8		
	Lying on the right side	224	8		
	Lying on the left side	225	8		

Given results relate to delivered samples only.

TC – sample after temperature conditioning

¹⁾ Estimation of conformity/nonconformity was assessed based on binary statement with guard band; acceptance level (AL) = tolerance limit (TW) – guard band (w); w is equal to expanded uncertainty (U95). Risk of incorrect acceptance ≤2.5%.

TEST RESULTS OF EXHALATION RESISTANCE according to EN 149:2001 + A1:2009

Test object: filtering half masks model VS005 FFP2 NR; product code: S27M11H4S28

No. of sample	The dummy head positions	Exhalation resistance, Pa (flow rate 2.7 dm ³ s ⁻¹)		Requirements in accordance with EN 149:2001 + A1:2009 (tolerance limit - TW)	Estimation of conformity / nonconformity with the standard ¹
		Measured value	Uncertainty (U95)		
05 SW	Facing directly ahead	233	9	Requirements in accordance with EN 149:2001 + A1:2009 (tolerance limit - TW) FFP1 ≤ 300 Pa FFP2 ≤ 300 Pa FFP3 ≤ 300 Pa	Filtering half masks fulfill requirements given in p. 7.16 of the EN 149:2001 + A1:2009 standard for exhalation resistance in the range of the first, the second and the third protection class (FFP1, FFP2, FFP3).
	Facing vertically upwards	237	9		
	Facing vertically downwards	233	9		
	Lying on the right side	229	9		
	Lying on the left side	235	9		
06 SW	Facing directly ahead	228	8		
	Facing vertically upwards	236	9		
	Facing vertically downwards	230	9		
	Lying on the right side	231	9		
	Lying on the left side	232	9		
07 SW	Facing directly ahead	240	9		
	Facing vertically upwards	242	9		
	Facing vertically downwards	238	9		
	Lying on the right side	236	9		
	Lying on the left side	239	9		

Given results relate to delivered samples only.

SW – sample after the simulated wearing treatment

¹) Estimation of conformity/nonconformity was assessed based on binary statement with guard band; acceptance level (AL) = tolerance limit (TW) – guard band (w); w is equal to expanded uncertainty (U95). Risk of incorrect acceptance ≤2.5%

END OF TEST REPORT

12.04.2023 (publication of English version of the letter dated 13.02.2023)

SO.542.35.2022.C2.44

Mask Authority sp. z o.o.Targowa 4
52-326 Wrocław
Poland

Dear Sir or Madam,

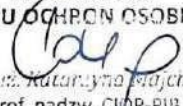
With reference to the control carried out according to the contract No. C2/44/2021/1437 and the module C2 of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016, please find enclosed the laboratory test report No. 610/CR/2022/NO dated 01.12.2022 and the report on the product check of personal protective equipment.

Following the product check results, we confirm that the tested samples of *Filtering half masks type VS005 FFP 2 NR* covered by the EU type examination certificate No. UE/540/2021/1437, ed. 4 issued by CIOP-PIB meet the requirements specified in the harmonised standard that is the basis for their assessment and conform to the type defined in the abovementioned certificate.

Accordingly, we confirm that the products covered by the aforementioned certificate meet the applicable basic health and safety requirements of the Regulation (EU) 2016/425.

Taking into account the above positive results of the control carried out, we hereby confirm that the production of the products covered by the EU type examination certificate No. UE/540/2021/1437, ed. 4 is homogeneous.

Yours sincerely,

KIEROWNIK
ZAKŁADU OCHRONY OSOBISTYCH

dr hab. inż. Katarzyna Sójchrzyska
prof. nadzw. CIOP-PIB

CENTRAL INSTITUTE FOR LABOUR PROTECTION – NATIONAL RESEARCH INSTITUTE NOTIFIED BODY NO. 1437 00-701 Warszawa, ul. Czerniakowska 16 CENTRE FOR CERTIFICATION OF PERSONAL PROTECTIVE AND WORKING EQUIPMENT 90-133 Łódź, ul. Wierzbowa 48	REPORT on product check according to module C2 No. 35/2022	Agreement No. C2/44/2021/1437 dated 08.02.2021 Page 1/3
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1. Name and address of the manufacturer

Mask Authority Sp. z o.o., Targowa 4, 52-326 Wrocław, Poland

2. Object of the check

Table 1: Personal protective equipment subject to checking under agreement

Number of the EU type-examination certificate, number of the notified body	Name of the product, type, model, symbol of PPE	Identification of the document which constitutes the basis for issuing an EU type-examination certificate
UE/540/2021/1437, ed. 4	Filtering half mask type VS005 FFP2 NR	EN 149:2001+A1:2009

3. Purpose and scope of the check

Product samples for carrying out laboratory tests and checks in order to verify homogeneity of production and conformity of the personal protective equipment specified in table 1 to type defined in a relevant EU type-examination certificate and compliance with applicable essential health and safety requirements in accordance with Regulation 2016/425.

4. Check date: 20.10.2022

Date of previous check: not applicable

5. Check site: Mask Authority Sp. z o.o., Targowa 4, 52-326 Wrocław, Poland

6. Checked by Mr Krzysztof Łęzak - Centre for Certification of Personal Protective and Working Equipment CIOP-PIB

Samples taken by Mr Krzysztof Łęzak – Centre for Certification of Personal Protective and Working Equipment CIOP-PIB

Observed by Ms Ewelina Głabala - Centre for Certification of Personal Protective and Working Equipment CIOP-PIB

Manufacturer's representative: Ms Marlena Hodowana - Mask Authority Sp. z o.o.

7. Criteria for the check

- 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,
- Agreement for supervised product checks according to module C2,
- Procedure POZ-02 Supervised product checks at random intervals according to module C2,
- EU type-examination certificate for personal protective equipment covered by the agreement *(as specified in item 2 of the report)*
- technical and technological documentation of personal protective equipment,
- previous check report - not applicable.

CENTRAL INSTITUTE FOR LABOUR PROTECTION – NATIONAL RESEARCH INSTITUTE NOTIFIED BODY NO. 1437 00-701 Warszawa, ul. Czerniakowska 16 CENTRE FOR CERTIFICATION OF PERSONAL PROTECTIVE AND WORKING EQUIPMENT 90-133 Łódź, ul. Wierzbowa 48	REPORT on product check according to module C2 No. 35/2022	Agreement No. C2/44/2021/1437 dated 08.02.2021 Page 2/3
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8. Results of laboratory tests and checks of samples taken during the check

Table 2: Results of laboratory tests and checks of samples taken during the check

Name of the product, type, model, symbol of PPE	Parameter tested	Results of parameter tested	Results of conformity assessment of			
			parameter tested in accordance with the standard	parameter tested in accordance with the EU type-examination certificate's records	marking in accordance with the EU type-examination certificate's records	manufacturer's instructions and information in accordance with the technical documentation referred to in the EU type-examination certificate
Filtering half mask type VS005 FFP2 NR	Flammability	Filtering half masks - new and after thermal conditioning do not burn	Filtering half masks fulfill the requirements given in p. 7.11 of the EN 149:2001 +A1:2009 standard	Compliance with the certificate No. UE/540/2021 /1437 ed. 4	Compliance of the filtering half masks' marking with the certificate No. UE/540/2021 /1437 ed. 4	Compliance of the manufacturer's information attached to the filtering half mask type VS005 FFP2 NR with the technical documentation of the product (edition 04 dated 17.05.2022) and instructions for use dated 09.03.2022 submitted to EU type examination
	CO ₂ content in inhaled air	Average value of CO ₂ content in inhaled air: (0.68 ± 0.04)% - new filtering half masks	Filtering half masks fulfill the requirements given in p. 7.12 of the EN 149:2001 +A1:2009 standard	Compliance with the certificate No. UE/540/2021 /1437 ed. 4		
	Practical performance test	Filtering half masks do not have imperfection related to wearer's acceptance - new filtering half masks	Filtering half masks fulfill the requirements given in p. 7.7 of the EN 149:2001 +A1:2009 standard	Compliance with the certificate No. UE/540/2021 /1437 ed. 4		

CENTRAL INSTITUTE FOR LABOUR PROTECTION – NATIONAL RESEARCH INSTITUTE NOTIFIED BODY NO. 1437 00-701 Warszawa, ul. Czerniakowska 16 CENTRE FOR CERTIFICATION OF PERSONAL PROTECTIVE AND WORKING EQUIPMENT 90-133 Łódź, ul. Wierzbowa 48	REPORT on product check according to module C2 No. 35/2022	Agreement No. C2/44/2021/1437 dated 08.02.2021 Page 3/3
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9. Final conclusions

The evaluation of laboratory test results of selected parameters characterizing the properties of the Filtering half masks type VS005 FFP2 NR, presented in table 2 confirmed compliance with the corresponding requirements of the harmonized standard EN 149:2001+A1:2009 constituting the basis for issuing the EU-type examination certificate No. UE/540/2021/1437, edition 4.

During the inspection, it was confirmed that the product marking and manufacturer's information comply with the technical documentation of the products submitted for this check and with the requirements of the EN 149:2001+A1:2009 standard in this regard.

The results of the inspection confirm that the manufactured products covered by the above-mentioned certificate are in accordance with the type described in the EU type-examination certificate and with the essential requirements of Regulation (EU) 2016/425 regarding health and safety.

10. Rules for dissemination of the report on product check

- Centre for Certification of Personal Protective and Working Equipment of CIOP-PIB – prohibited, except for the cases described in the agreement
- Assessed organisation – at the management's discretion, however, always in full

Lodz, 31.01.2023 (publication of Polish version of this report)

Lodz, 12.04.2023 (publication of English version of this report)

Place, date

A. Stefko
.....
Signature of the person performing the check

Attachments:

1. Test Report No.: 610/CR/2022/NO dated 01.12.2022 (in Polish version)
2. Report of samples collection (only for CIOP-PIB copy)

Distribution list:

1. Mask Authority Sp. z o.o., Targowa 4, 52-326 Wrocław, Poland
2. Centre for Certification of Personal Protective and Working Equipment of CIOP-PIB, 90-133 Łódź, ul. Wierzbowa 48, Poland

Mask Authority

ul. Targowa 4, 52-326 Wrocław, Poland

VS005, FFP2 NR

EN 149:2001 + A1:2009

LOT: 09/08/2021/A/1/2

09/08/2026

CE 1437

virshields

FFP2



FFP2



Effektiver Schutz vor Staub und Aerosolen ✓

Optimaler Sitz durch Nasenclip ✓

5-Schuttlagen 3D-geformt ✓

Hoher Schutzfaktor ✓

Einzelverpackt ✓



FILTRIERENDE HALBMASKE VS005

FFP2 NR



www.virshields.com

10 Stück



EN

Wash hands with soap for 30 seconds

DE

Hände 30 Sekunden mit Seife waschen

2



Place mask on

Maske aufsetzen



EN

Put the mask under the chin, up the nose clip

DE

Maske unter dem Kinn ansetzen, den Nasenbügel nach oben



Put the rubber band around your ears

Gummiband um die Ohren legen



EN

Use both hands to adjust the nose clip to the bridge of the nose

DE

Mit beiden Händen den Nasenbügel an den Nasenrücken anpassen



Press on mask and check fit

Maske andrücken und Sitz kontrollieren

SAFETY NOTICE:
DO NOT USE DAMAGED MASKSSICHERHEITSHINWEIS:
BESCHÄDIGTE MASKEN NICHT VERWENDEN

REV.1_04.12.2020



Mask Authority Sp. z o.o.

ul. Targowa 4, 52-326 Wrocław, Poland

www.virshields.com

info@virshields.com

LOT

09082021 VS005



09082021



09082026

Das Ablaufdatum ist gültig wenn das Produkt entsprechend der Anweisungen auf der Verpackung aufbewahrt wird.



EN 149:2001+A1:2009

CE 1437



Effective protection against dust and aerosols ✓

Perfect fit thanks to noseclip ✓

5-protective layers 3D-formed ✓

High protection factor ✓

Single packed ✓



FILTERING HALF MASK VS005

FFP2 NR



www.virshields.com

10 Pieces

Produktname: Virshields Filtrierende Halbmaske VS005 FFP2 NR

Materialzusammensetzung: Produkt hergestellt aus nicht-gewebten Polypropylen-Stoffen, Meltblown und Heißluftbaumwolle

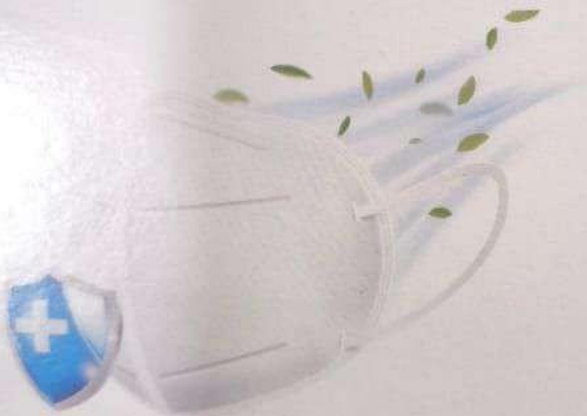
Verwendung: eine filtrierende Halbmaske ist ein Teil der persönlichen Schutzausrüstung und schützt den Träger vor den schädlichen Auswirkungen von Luftverunreinigungen in Form von festen und/oder flüssigen Partikeln (Stäube, Dämpfe und Nebel).

Aufbewahrung: Bewahren Sie die Masken in der Originalverpackung, fern von kontaminierten Orten, Staub, Sonnenlicht, extremen Temperaturen, hoher Feuchtigkeit oder Chemikalien, bei einer Temperatur von (-20°C) bis $(+30^{\circ}\text{C})$ und einer maximalen Luftfeuchtigkeit von 80% (RH) auf.

 Bitte lesen Sie vor der Benutzung die Gebrauchshinweise aufmerksam durch, da diese wichtige Informationen für den Verwender beinhalten. Die Gebrauchshinweise sowie die Konformitätserklärung sind einzusehen unter www.virshields.com

PPE Regulation (EU) 2016/425, cat.III, Notified Body 1437 responsible for EU Type Examination (Module B) and Certification (Module C2):
CENTRALNY INSTYTUT OCHRONY PRACY - PAŃSTWOWY INSTYTUT BADAWCZY (CIOP-PIB), ul. Czerniakowska 1600-701 WARSZAWA

10 Stück



www.virshields.com

FILTRIERENDE HALBMASKE VS005





5 903796 604887 >

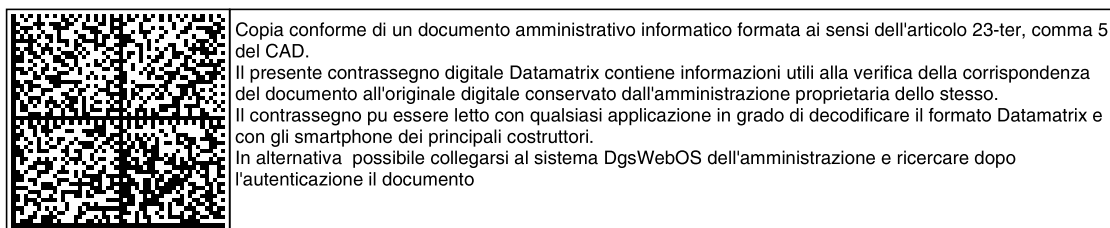




L' art. 23 del Codice dell'Amministrazione Digitale (Decreto Legislativo 7 marzo 2005, n. 82 e s.m.i.), riconosce alle copie analogiche di documenti informatici (es. la stampa di un certificato, un contratto, ecc.) la stessa efficacia probatoria dell'originale informatico da cui sono tratti se la loro conformità non viene espressamente disconosciuta (in giudizio). Diverso il caso in cui la conformità all'originale informatico, in tutte le sue componenti, sia attestata da un pubblico ufficiale autorizzato. In questo caso, infatti, per negare alla copia analogica di documento informatico la stessa efficacia probatoria del documento sorgente si rende necessaria la querela di falso.

Questo regime, di carattere generale, incontra alcune deroghe rispetto alle copie analogiche di documenti amministrativi informatici.

L'art. 23-ter del CAD prevede che sulle copie analogiche di documenti amministrativi informatici possa essere apposto un contrassegno a stampa (detto anche timbro digitale o glifo) che consente di accertare la corrispondenza tra le copie analogiche stesse e l'originale informatico (in esso deve essere codificato, infatti, il documento informatico o le informazioni necessarie a verificarne la corrispondenza all'originale in formato digitale). La verifica avviene grazie ad appositi software che leggono le informazioni contenute nel timbro digitale. I software necessari per l'attività di verifica devono essere gratuiti e messi liberamente a disposizione da parte delle amministrazioni.



Impronta del documento digitale originale: 414cb227ac47c905c9eb6c2c31d64e01

Identificativo del documento digitale originale: 650390

Protocollo: SoReSa-0010832-2025 05-06-2025 09:58:32

Ai Sig.ri Direttori Generali
Ai Sig.ri Provveditori
AA.SS.LL., AA.OO., AA.OO.UU., IRCSS
a mezzo pec

e p.c.
Pizzocri S.r.l.
A mezzo pec: pizzocri@pec.sm

Oggetto: Autorizzazione ex art. 19 Convenzione Rep. 80-2024. PROCEDURA APERTA PER L'AFFIDAMENTO DELLA FORNITURA DI MASCHERINE CHIRURGICHE, FACCIALI FILTRANTI FFP2 E FFP3 DESTINATI ALLE AA.SS. DELLA REGIONE CAMPANIA- lotto 3

Con riferimento alla fornitura in oggetto

vista la richiesta di autorizzazione ex art. 19 della Convenzione presentata dalla società Pizzocri S.r.l. ed acquisita al protocollo interno con n. SoReSa-0008653-2025 del 02/05/2025.

alla luce dell'istruttoria espletata ed acquisito il parere tecnico favorevole circa l'aggiornamento tecnologico proposto dalla Ditta

si autorizza, secondo le previsioni del Capitolato Tecnico di gara, alle medesime condizioni economiche contrattuali, la variazione dei prodotti come da richiesta che costituisce parte integrante e sostanziale della presente e come di seguito indicato:

LOTTO 3 - MASCHERINE FFP3 NR SENZA VALVOLA - NUOVO CODICE PRODOTTO MV99

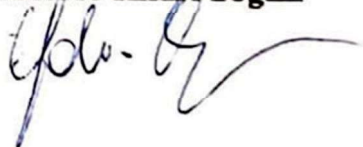
In allegato:

- Istanza di autorizzazione SoReSa-0008653-2025 del 02/05/2025
- Documentazione tecnica.

Distinti saluti.

So.Re.Sa. S.p.A.
Il Responsabile per l'esecuzione dei contratti
Avv. Gianmarco Massa


Avv. Fabio Aprea
Direttore Affari Legali



Segreteria So.Re.Sa SpA

Da: arealegale@pec.soresa.it
Inviato: venerdì 2 maggio 2025 11:30
A: Segreteria So.Re.Sa SpA
Oggetto: I: RICHIESTA VARIAZIONE CODICE PRODOTTO - CONVENZIONE N. 00000717 FORNITURA DI MASCHERINE CHIRURGICHE, FACCIALI FILTRANTI FFP2 E FFP3 DESTINATI ALLE AA.SS. DELLA REGIONE CAMPANIA
Allegati: PLICO TECNICO FFP2 - VS005 - ITA.pdf; PLICO TECNICO MASCHERINE MYS FFP3 NR- IT.pdf; PLICO TECNICO CHIRURGICHE COMPLETO 4 STRATI IIR XR001 - IT.pdf
Priorità: Alta



Direzione Affari Legali
Centro Direzionale Isola G3
80143 - Napoli
Tel 081.2128174
Fax 0817500012

Da: pizzocri@pec.sm <pizzocri@pec.sm>
Inviato: venerdì 2 maggio 2025 11:29
A: arealegale <arealegale@pec.soresa.it>
Cc: acquisizione.beni <acquisizione.beni@pec.aslna1centro.it>
Oggetto: RICHIESTA VARIAZIONE CODICE PRODOTTO - CONVENZIONE N. 00000717 FORNITURA DI MASCHERINE CHIRURGICHE, FACCIALI FILTRANTI FFP2 E FFP3 DESTINATI ALLE AA.SS. DELLA REGIONE CAMPANIA
Priorità: Alta

Buongiorno,
con la presente siamo a richiedere la variazione dei codici prodotto della fornitura della convenzione in oggetto, in quanto come precedentemente comunicato i modelli offerti in fase di gara attualmente sono fuori produzione. Vorremmo precisare che le caratteristiche tecniche dei prodotti sostitutivi rispettano il capitolato tecnico al 100%. Colgo l'occasione per allegare la documentazione tecnica dei nuovi prodotti. La variazione del codice prodotto è la seguente:

- **LOTTO 1 - MASCHERINE CHIRURGICHE A 4 STRATI DI TIPO IIR - NUOVO CODICE PRODOTTO XR001**
- **LOTTO 2 - MASCHERINE FFP2 NR SENZA VALVOLA - NUOVO CODICE PRODOTTO VS005**
- **LOTTO 3 - MASCHERINE FFP3 NR SENZA VALVOLA - NUOVO CODICE PRODOTTO MV99**

Restiamo in attesa di ricevere un gentile riscontro, per poter procedere con l'evasione degli ordini ricevuti da ASL NAPOLI 1 CENTRO che ci legge in copia.

A disposizione per qualsiasi altra informazione, saluto cordialmente.

Pizzocri S.r.l.

Via Fondo Ausa, 28 – Dogana (RSM) 47890

C.O.E. 29433 – N° iscr. 8747

C.F. PZZNCL94M04I577V – Tel. 0549/910442

Tel. +39 348/8645908 – pizzocri@pec.sm

Fax: 02/26411996 – Codice ISS 181537

MASCHERINE FFP3 NR SENZA VALVOLA CON ELASTICI AURICOLARI *CERTIFICATE COME DPI DI III CATEGORIA*

Firmato digitalmente da: NICOLO' PIZZOCRI
Luogo: San Marino
Data: 02/05/2025 10:56:54



Produttore:

Xiamen Miaoxing Technology Co.,Ltd

Address: 5Floor, No.333-4TongFuRoad, TongAn district,

Xiamen, China

www.xmmiaoxing.com

Importatore :Pizzocri S.r.l

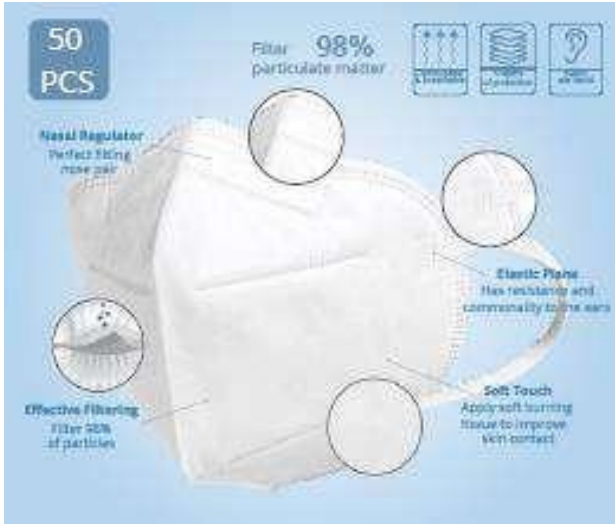
Via Fondo Ausa, 28 – 47891

Repubblica di San Marino

www.pizzocri.com

info@pizzocri.com

DATI PRINCIPALI DEL PRODOTTO



MATERIALE	TNT 100% Latex Free
MARCA	MYS
COLORE	BIANCO
MODELLO	MV99
PRODUTTORE	Xiamen Miaoxing Technology Co.,Ltd
RAPPRESENTANTE EUROPEO	LGAI Technological Center, S.A. (APPLUS)
CND	T0399
RDM	2527991
DPI	III CATEGORIA
DATA DI PRODUZIONE	10/2024
DATA DI SCADENZA	10/2027

UTILIZZO DEL PRODOTTO E CAMPO DI APPLICAZIONE

Le maschere FFP3 sono una categoria di maschere facciali filtranti che offrono un alto livello di protezione respiratoria. Sono progettate per filtrare particelle sottili, aerosol e sostanze nocive presenti nell'aria, garantendo una maggiore protezione rispetto alle maschere chirurgiche o alle maschere FFP3

Le principali caratteristiche e usi delle maschere FFP3 includono:

- Protezione da particelle sottili: Le maschere FFP3 sono progettate per filtrare almeno il 99% delle particelle in sospensione nell'aria, inclusi aerosol, polveri sottili, fumi e nebbie.
- Ambienti ad alto rischio: Le maschere FFP3 sono spesso utilizzate in ambienti in cui è presente un rischio elevato di esposizione a sostanze pericolose come agenti patogeni, polveri tossiche, amianto, fumi di saldatura e altre particelle fini nocive.
- Settori industriali: Sono ampiamente utilizzate nell'industria chimica, nelle lavorazioni di metalli, nell'edilizia, nell'industria farmaceutica e in altre situazioni lavorative dove la salute dei lavoratori può essere minacciata da sostanze dannose in sospensione nell'aria.
- Procedure mediche avanzate: In alcune situazioni mediche, come l'esecuzione di procedure invasive o trattamenti su pazienti con malattie altamente contagiose, le maschere FFP3 possono essere impiegate per proteggere gli operatori sanitari.
- Protezione individuale: Le persone con sistemi immunitari compromessi o condizioni mediche che le rendono particolarmente suscettibili alle infezioni potrebbero utilizzare maschere FFP3 per una protezione aggiuntiva quando sono esposte a ambienti con potenziali patogeni.
- Emergenze ambientali: In caso di emergenze ambientali, come incendi, eruzioni vulcaniche o altre situazioni in cui l'aria è contaminata da sostanze tossiche, le maschere FFP3 possono essere utilizzate per aiutare le persone a respirare in modo sicuro.

CARATTERISTICHE SPECIFICHE DEL PRODOTTO

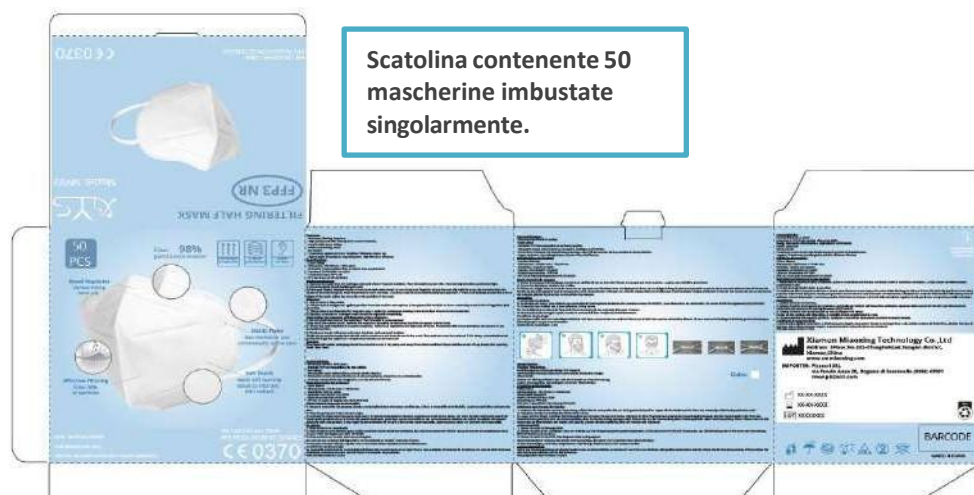
• Elastici auricolari, fissati al corpo maschera • Cuscinetto poggia naso in gommapiuma • Senza valvola di espirazione • Prevenzione da PM3 • Confortevole da indossare • Alta efficienza • NO utilizzo della colla • NO formaldeide • Adatta a tutti i tipi di viso • senza uso di graffette metalliche • Protezione del mento, naso e bocca • Nasello regolabile • Nichel-free	• Latex free • Monouso • Prodotto biocompatibile • Realizzata in materiale resistente ed anallergico • Design che permette una perfetta aderenza al viso • Efficienza di filtraggio: Velocità di filtrazione del particolato NON oleoso >= 99% • Taglia unica
--	--

CERTIFICAZIONI E TEST REPORT

CERTIFICATO CE	Modulo B: rilasciato da Notified Body no. 0370 - LGAI TECHNOLOGICAL CENTER, S.A. (APPLUS) Certificato n. 0370-5369-PPE/B Conforme alla direttiva europea 2016/425
	Modulo C2: rilasciato da Notified Body no. 0370 - LGAI TECHNOLOGICAL CENTER, S.A. (APPLUS) Certificato n. 0370-7071-PPE/C2 Conforme alla direttiva europea 2016/425
DICHIARAZIONE DI CONFORMITA' SECONDO LA NORMATIVA EUROPEA EU 2016/425	A CURA DEL PRODUTTORE
TEST DI LABORATORIO CHE ATTESTA LA CONFORMITA' ALLA NORMATIVA EUROPEA EN 149:2001 + A1:2009	Precise Testing & Certification (Guangdong) Co., Ltd. (PTC) N. TEST RIFERITO AL MODULO B: PTC21012905401C-EN01 N. TEST RIFERITO AL MODULO C2: PTC24011707601C-EN01

CONFEZIONAMENTO

Confezionamento (1° Livello)	1 (una) mascherina in una bustina sigillate di plastica
Confezionamento (2° Livello)	50 (cinquanta) bustine sigillate di plastica (50 mascherine) in una scatolaina di cartone.
Confezionamento (3° Livello)	40 (quaranta) scatoline di cartone (2000 mascherine) in uno scatolone
PESO E DIMENSIONI DEL CARTONE	Peso 17 Kg – Dimensioni 67*66*34 cm



Cartone robusto che garantisce la conservazione
67*66*34cm / 17kg

Ogni confezione riporta tutte le informazioni previste dalla normativa vigente e quelle necessarie a garantire una utilizzazione corretta e sicura del dispositivo. Gli imballaggi esterni sono di materiale resistente, tali da poter essere impilati e riportano il tipo, la quantità, la scadenza e il codice del prodotto. Imballo e confezioni sono "a perdere". Ogni singola scatola ed ogni singola busta esterna riportano i dati previsti dalla Direttiva 2007/46/CE, D.Lgs. 25 gennaio 2010, n. 37. Sulla confezione è riportata la destinazione d'uso. I dispositivi sono contenuti in confezioni che ne garantiscano la corretta conservazione ed il facile immagazzinamento per sovrapposizione. Le singole confezioni sono imballate in scatoloni robusti e a tenuta di polvere. Il materiale di confezionamento è resistente e tale da garantire la corretta conservazione del prodotto. Tutte le singole confezioni e imballi di spedizione sono provvisti di etichette indelebili che riportano, in lingua italiana, tutte le iscrizioni previste dalla normativa vigente. Sulla confezione sono riportate, in lingua italiana, tutte le informazioni previste dalla normativa vigente e necessarie per garantire una utilizzazione corretta e sicura del prodotto.

ISTRUZIONI D'USO

1. Rimuovere la maschera dalla confezione, aprire e controllare se in buone condizioni. Metti la maschera sul mento. La clip al naso dovrebbe essere posizionata in alto.
2. Posizionare gli elastici dietro le orecchie
3. Posiziona le dita tra la punta del naso e premi verso l'interno mentre muovi la punta delle dita lungo la clip per il naso finché la clip per il naso non viene premuta nella forma del ponte nasale per garantire che la maschera sia indossata correttamente.
4. Effettuare un controllo della tenuta dell'utente prima di utilizzare ciascun indumento. Se ci sono perdite d'aria intorno al naso o ai bordi della maschera, regolare la clip per il naso o la posizione della maschera.



厦门妙杏科技有限公司
厦门市同安区同福路 333 号四号厂房第五层之一
邮编: 361100
电话: +86-0592-7036016
www.xmmiaoxing.com

Xiamen Miaoxing Technology Co.,Ltd
5Floor,No.333-4TongFuRoad,TongAn district ,Xiamen ,China
361100
+86-0592-7036016
www.xmmiaoxing.com

EU DECLARATION OF CONFORMITY

DICHIARAZIONE DI CONFORMITÀ UE

Personal Protective Equipment/Dispositivi di protezione individuale:

Brand / Marca:	MYS
Name / Nome:	Filtering half mask
Model / Modello:	MV99
Standard / Standard:	EN 149:2001+A1:2009
Class / Classe	FFP3 NR
Manufacturer / Produttore	Xiamen Miaoxing Technology Co.,Ltd
Manufacturer Address / Indirizzo del produttore	5Floor,No.333-4TongFuRoad,TongAn district ,Xiamen ,China
Module B certificate NO. / Certificato modulo B n.	0370-5369-PPE/B
Module C2 certificate NO. / Certificato modulo C2 n.	0370-7071-PPE/C2

This declaration of conformity is issued under the sole responsibility of the manufacturer:

La presente dichiarazione di conformità viene rilasciata sotto la sola responsabilità del produttore:

Xiamen Miaoxing Technology Co.,Ltd

The object of the declaration described above is in conformity with the relevant Union harmonization legislation: Personal Protective Equipment Regulation (EU) 2016/425.

L'oggetto della dichiarazione sopra descritta è conforme alla pertinente normativa di armonizzazione dell'Unione: Regolamento sui dispositivi di protezione individuale (UE) 2016/425.

The fulfillment of the relevant health and safety requirements set out in Annex II has been demonstrated.

È stato dimostrato il rispetto dei pertinenti requisiti di salute e sicurezza di cui all'allegato II.

The notify body/ L'organismo notificato:

LGAI TECHNOLOGICAL CENTER (APPLUS),

Campus UAB, Ronda de la Font del Carme s/n, E-08193 Bellaterra (Barcelona), Spain,

Notified Body Number:0370

performed the EU type-examination (Module B) and issued the EU type-examination certificate with notified body number 0370.

ha eseguito l'esame UE del tipo (modulo B) e ha rilasciato il certificato di esame UE del tipo con numero dell'organismo notificato 0370.

The PPE is subject to the conformity to type assessment procedure based on internal production control plus supervised product checks at random intervals (Module C2) set out in the Regulation (EU) 2016/425 under surveillance of the notified body LGAI TECHNOLOGICAL CENTER (APPLUS), NB 0370.

Il DPI è soggetto alla procedura di valutazione della conformità al tipo basata sul controllo interno della produzione e su controlli supervisionati del prodotto a intervalli casuali (Modulo C2) stabiliti nel Regolamento (UE) 2016/425 sotto la sorveglianza dell'organismo notificato LGAI TECHNOLOGICAL CENTER (APPLUS), NB 0370.

Signed for and on behalf of:

Sam Liu
CEO
2024/9/18



Sam Liu



Notified Body No. 0370

CERTIFICADO DE EXAMEN UE DE TIPO

EU-TYPE EXAMINATION CERTIFICATE

No. **0370-5369-PPE/B**

ORGANISMO NOTIFICADO Nº NOTIFIED BODY NUMBER	0370 - LGAI TECHNOLOGICAL CENTER (APPLUS)
SOLICITANTE / FABRICANTE APPLICANT / MANUFACTURER	Xiamen Miaoxing Technology Co.,Ltd 5Floor,No.333-4TongFuRoad,TongAn district ,Xiamen ,China
PLANTA DE PRODUCCIÓN PRODUCTION SITE	Xiamen Miaoxing Technology Co.,Ltd 5Floor,No.333-4TongFuRoad,TongAn district ,Xiamen ,China
REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD / APPLICABLE REGULATION TO GIVE CONFORMITY: REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT	
PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD CONFORMITY ASSESSMENT PROCEDURE	Módulo // Module: B EXAMEN UE DE TIPO / EU TYPE EXAMINATION
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) IDENTIFICATION OF THE PPE (TYPE NUMBER)	Ref.: MV99 Filtering half mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE	FFP3 NR
NORMAS ARMONIZADAS / HARMONISED STANDARDS	EN 149:2001 + A1:2009 Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. Requisitos, ensayos, marcado. EN 149:2001 + A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking
FECHA DE EMISIÓN / ISSUE DATE	10/03/2021
VALIDEZ HASTA / VALIDITY UNTIL	10/03/2026
El presente certificado se mantendrá vigente durante 5 años siempre que el producto descrito no sea modificado y cumpla los requisitos esenciales de salud y seguridad establecidos en el Reglamento (UE) 2016/425. Para asegurar dicho cumplimiento, este certificado deberá ir acompañado de la documentación correspondiente a la Evaluación de Conformidad con el tipo según módulo C2, D (realizada por un Organismo Notificado, según frecuencia establecida). This certificate will remain valid for 5 years as long as the indicated product is not modified and fulfills the essential requirements of health and safety established in (EU) Regulation 2016/425. To ensure such compliance, this certificate must be accompanied by the documentation corresponding to the Conformity Assessment to type according to C2, D(carried out by a Notified Body according, to the established frequency).	



Applus⁺
LGAI Technological Center, S.A.
Xavier Ruiz Peña

Managing Director, Product Conformity B.U.

Este documento carece de validez sin su anexo técnico, cuyo número coincide con el del certificado.
This document is not valid without its technical annex, whose number coincides with the number of certificate.

Puede comprobarse la validez de este certificado en nuestra página web / You can check the validity of this certificate on our website:
www.appluslaboratories.com/certified_products



ANEXO TÉCNICO TECHNICAL ANNEX

0370-5369-PPE/B

I. MODELOS INCLUIDOS EN EL CERTIFICADO

REFERENCES INCLUDED IN THIS CERTIFICATE

MARCA BRAND	MYS
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) IDENTIFICATION OF THE PPE (TYPE NUMBER)	Ref.: MV99 Filtering half mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE	FFP3 NR
DESCRIPCIÓN DESCRIPTION	MEDIA MÁSCARA FILTRANTE SIN VÁLVULA, DE TIPO PLEGABLE VERTICAL, DE 5 CAPAS, DE COLOR BLANCO, CON LAZOS DE OREJA CON GANCHO, CON ALMOHADILLA NASAL Y CLIP NASAL INTERONO. TAMAÑO: 160mm×105mm. // VALVELESS FILTERING HALF MASK, VERTICAL FOLDING TYPE, 5 LAYERS, WHITE COLOUR, WITH EARLOOPS WITH HOOK, WITH NOSE BRIDGE PAD AND INTERIOR NOSE CLIP. SIZE: 160mm×105mm
INFORME DE ENSAYO TEST REPORT	PTC21012905401C-EN01 issued by Precise Testing & Certification (Guangdong) Co.,Ltd.(PTC)



中国认可
国际互认
检测
TESTING
CNAS L5772

Test Report

EN 149:2001+A1:2009 protective devices. Filtering half masks to protect against particles. Requirements, testing, marking

Product: Filtering half mask
Report No.: PTC21012905401C-EN01
Client: Xiamen Miaoxing Technology Co.,Ltd
Client Address: 5Floor,No.333-4TongFuRoad,TongAn district ,Xiamen ,China
Manufacturer: Xiamen Miaoxing Technology Co.,Ltd
Manufacturer Address: 5Floor,No.333-4TongFuRoad,TongAn district ,Xiamen ,China
Contact: Mr.Liu
Model(s): MV99
Classification: FFP3 NR
Date of Tests: 2021.02.26~2021.03.04

Signed for and on Behalf of PTC

Prepare by:

Checked by:

Approved by:

Arme

gmc

Jim Mo



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Precise Testing & Certification (Guangdong) Co., Ltd. (PTC)

Building 1, No. 6, Tongxin Road, Dongcheng Street, Dongguan, Guangdong, China.
Tel: 86-769-38808222 Fax: 86-769-38826111 <http://www.ptc-testing.com>



Test Report

Report No.:PTC21012905401C-EN01

Issue Date: Mar.05, 2021

Page 2 of 14

Summary of assessment

Clause	Assessment
7.3 Visual inspection	NOT TESTED
7.4 Packaging	PASS
7.5 Material	PASS
7.6 Cleaning and disinfecting	N/A
7.7 Practical performance	PASS
7.8 Finish of parts	PASS
7.9.1 Total inward leakage	PASS
7.9.2 Penetration of filter material	PASS
7.10 Compatibility with skin	PASS
7.11 Flammability	PASS
7.12 Carbon dioxide content of the inhalation air	PASS
7.13 Head harness	PASS
7.14 Field of vision	PASS
7.15 Exhalation valve	N/A
7.16 Breathing resistance	PASS
7.17 Clogging	N/A
7.18 Demountable parts	PASS
9 Marking	NOT TESTED

Remark:

PASS: comply with requirement of standard

N/A: not application

NOT TESTED: the clause were not required

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Test Result:

Requirement	Test Result	Conclusion
7.3 Visual inspection The visual inspection shall also include the marking and the information supplied by the manufacturer.	Not tested	Not tested
7.4 Packaging Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	In accordance with the requirement.	Pass
7.5 Material Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	No mechanical failure after undergoing the conditioning described in 8.3.1, No collapse when conditioned in accordance with 8.3.1 and 8.3.2.	Pass
7.6 Cleaning and disinfecting If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.	Single shift use only	N/A
7.7 Practical performance The particle filtering half mask shall undergo practical performance tests under realistic conditions	No imperfections	Pass
7.8 Finish of parts Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs.	Pass

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7.9.1 Total inward leakage

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than 25 % for FFP1, 11 % for FFP2, 5 % for FFP3

and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22 % for FFP1, 8 % for FFP2, 2 % for FFP3.

FFP3, Test results are shown in Annex A Table 7.9.1-A&B

Pass

7.9.2 Penetration of filter material

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤ 20%	≤ 20%
FFP2	≤ 6%	≤ 6%
FFP3	≤ 1%	≤ 1%

FFP3 , Test results are shown in Annex A Table 7.9.2.

Pass

7.10 Compatibility with skin

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

No irritation or any other adverse effect to health.

Pass

7.11 Flammability

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

Test results are shown in Annex A Table 7.11.

Pass

7.12 Carbon dioxide content of the inhalation air

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)

Test results are shown in Annex A Table 7.12.

Pass

7.13 Head harness

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

Head harness can be donned and removed easily, adjustable or self-adjusting and

Pass

The head harness shall be adjustable or self-adjusting and shall be

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sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

have sufficiently robust to hold the particle filtering half mask firmly.

7.14 Field of vision

The field of vision is acceptable if determined so in practical performance tests.

Pass the practical performance tests.

Pass

7.15 Exhalation valve

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.

No exhalation valve

N/A

Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

7.16 Breathing resistance

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

FFP3. Test results are shown in Annex A Table 7.16.

Pass

7.17 Clogging

7.17.2 Breathing resistance

Valved particle filtering half masks:

After clogging the inhalation resistances shall not exceed:

FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow

The exhalation resistance shall not exceed 3 mbar at 160 L/min

Single shift use only.

N/A

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continuous flow

Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed:

FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow

7.17.3 Penetration of filter material

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤ 20%	≤ 20%
FFP2	≤ 6%	≤ 6%
FFP3	≤ 1%	≤ 1%

7.18 Demountable parts

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand

Comply

Pass

9 Marking

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.1.2 Type-identifying marking.

9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable.

Example: FFP2 R D.

9.1.4 The number and year of publication of this European Standard.

9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.

9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using

Not tested

Not tested

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the pictogram as shown in Figure 12b.

9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.

9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.

9.2 Particle filtering half mask

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space.

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

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Annex A: Summarization of Test Data

Table 7.9.1-A: Inward Leakage Test Data

Test specification: EN 149:2001+A1:2009 Clause 8.5

Subject	Sample No.	Condition	Walk (%)	Head Side/side (%)	Head up/down (%)	Talk (%)	Walk (%)	Mean (%)
Lv	1	A.R	1.2	1.4	1.6	1.2	1.2	1.3
Li	2	A.R	1.2	1.3	1.4	1.4	1.5	1.4
Zhong	3	A.R	1.1	1.4	1.6	1.5	1.1	1.3
Xu	4	A.R	1.3	1.3	1.4	1.2	1.2	1.3
Ma	5	A.R	1.4	1.9	1.8	1.6	1.2	1.6
Chen	6	T.C	1.2	1.7	1.7	1.5	1.5	1.5
Chen	7	T.C	1.2	1.5	1.5	1.7	1.0	1.4
Zhuo	8	T.C	1.0	1.5	1.2	1.5	1.2	1.3
Chen	9	T.C	1.5	1.5	1.5	1.7	1.7	1.6
Zhang	10	T.C	1.1	1.7	1.9	1.3	1.4	1.5

Table 7.9.1-B: Facial dimension

Subject	Face Length	Face Width	Face Depth	Mouth Width
Lv	113	139	104	53
Li	120	135	112	55
Zhong	108	135	106	56
Xu	120	150	120	70
Ma	130	170	130	80
Chen	110	160	90	40
Chen	115	145	110	50
Zhuo	103	146	100	50
Chen	110	145	95	40
Zhang	144	141	101	54

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Table 7.9.2: Penetration of filter material

Test specification: EN 149:2001+A1:2009 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	0.1	Pass
		12	0.1	
		13	0.1	
	Simulated wearing treatment	14	0.4	
		15	0.5	
		16	0.1	
	Mechanical strength + Temperature conditioned	17	0.1	
		18	0.2	
		19	0.4	
Paraffin oil test	As received	20	0.1	
		21	0.1	
		22	0.1	
	Simulated wearing treatment	23	0.2	
		24	0.2	
		25	0.2	
	Mechanical strength + Temperature conditioned	26	0.1	
		27	0.1	
		28	0.1	

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Table 7.11: Flammability

Test specification: EN 149:2001+A1:2009 Clause 8.6

Condition	Sample No.	Result	Assessment
As received	29	No burn	Pass
	30	No burn	
Temperature conditioned	31	No burn	
	32	No burn	

Table 7.12: Carbon dioxide content of the inhalation air

Test specification: EN 149:2001+A1:2009 Clause 8.7

Condition	Sample No.	Result (%)		Assessment
As received	33	0.05	Mean value: 0.05	Pass
	34	0.05		
	35	0.04		

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Table 7.16: Breathing resistance (mbar)

Test specification: EN 149:2001+A1:2009 Clause 8.9

As received	Flow Rate		36					37					38				
	Inhalation	30 l/min	0.36					0.37					0.35				
		95 l/min	1.29					1.33					1.30				
	Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			1.85	1.89	1.84	1.90	1.88	1.80	1.80	1.79	1.83	1.83	1.78	1.77	1.75	1.77	1.79
Simulated wearing treatment	Flow Rate		39					40					41				
	Inhalation	30 l/min	0.40					0.40					0.40				
		95 l/min	1.43					1.45					1.47				
	Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			2.02	2.03	2.00	2.07	2.03	2.04	2.05	2.04	2.05	2.00	2.06	2.06	2.05	2.03	2.04
Temperature conditioned	Flow Rate		42					43					44				
	Inhalation	30 l/min	0.33					0.33					0.34				
		95 l/min	1.18					1.22					1.12				
	Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			1.82	1.89	1.84	1.89	1.85	1.83	1.84	1.82	1.81	1.85	1.88	1.86	1.83	1.83	1.82
Assessment	Pass																

A: Facing directly ahead B: Facing vertically upwards C: Facing vertically downwards

D: Lying on the left side E: Lying on the right side

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Test Report

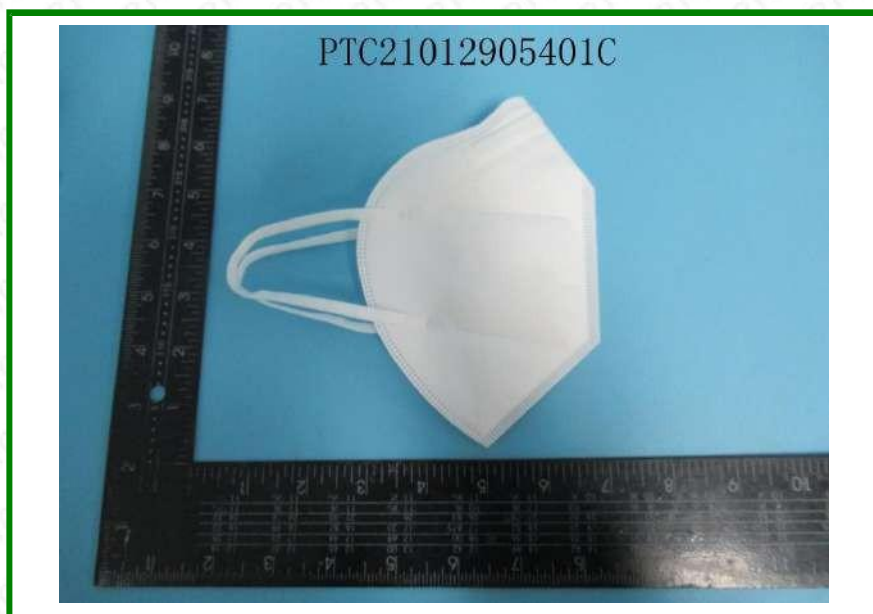
Report No.:PTC21012905401C-EN01

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Test	Uncertainty
Total inward leakage	3.8%
Penetration of filter material(NaCl)	3.5%
Penetration of filter material(Paraffin oil)	4.2%
Carbon dioxide content of the inhalation air	4.5%
Breathing resistance(30L/min)	5.2%
Breathing resistance(95L/min)	5.4%
Breathing resistance(160)L/min)	6.0%

Photo(s) of Sample:



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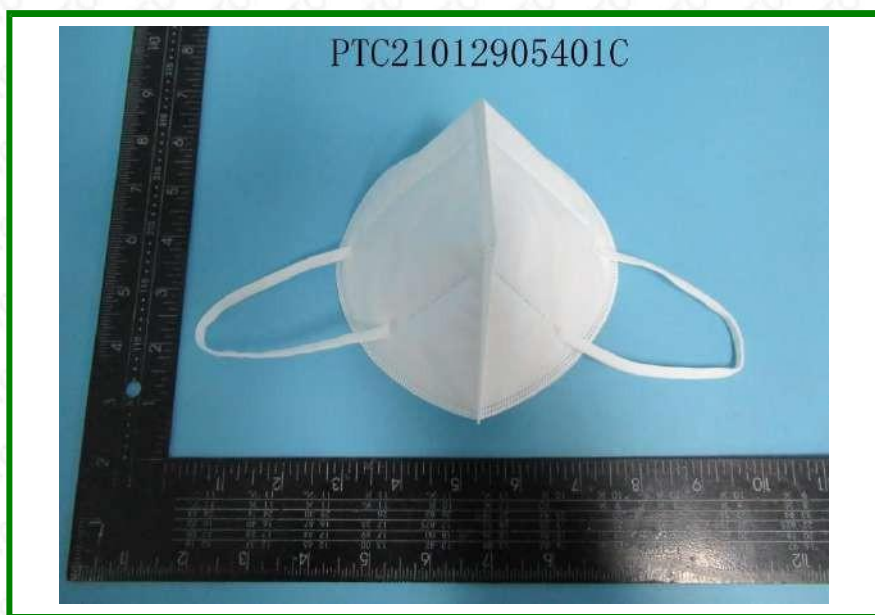


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CERTIFICADO DE CONFORMIDAD CON EL TIPO CONFORMITY TO TYPE CERTIFICATE

LGAI Technological Center, S.A. (APPLUS)
Organismo Notificado / *Notified Body* Nr. 0370

No. **0370-7071-PPE/C2**

SOLICITANTE / FABRICANTE APPLICANT / MANUFACTURER	Xiamen Miaoxing Technology Co.,Ltd 5Floor, No.333-4TongFuRoad, TongAn district, Xiamen, China
PLANTA DE PRODUCCIÓN PRODUCTION SITE	Xiamen Miaoxing Technology Co.,Ltd 5Floor, No.333-4TongFuRoad, TongAn district, Xiamen, China
REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD / APPLICABLE REGULATION TO GIVE CONFORMITY: REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT	
PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD CON EL TIPO CONFORMITY ASSESSMENT PROCEDURE TO TYPE	Módulo // Module: C2 BASADA EN EL CONTROL INTERNO DE LA PRODUCCIÓN MÁS EL CONTROL SUPERVISADO DE LOS PRODUCTOS A INTERVALOS ALEATORIOS BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED CONTROL OF PRODUCTS AT ALEATORY INTERVALS
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) IDENTIFICATION OF THE PPE (TYPE NUMBER)	Ref.: MV99 Filtering half mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE	FFP3 NR
FECHA DE EMISIÓN / ISSUE DATE	06/03/2024
VALIDEZ HASTA / VALIDITY UNTIL:	06/03/2025
El presente certificado se mantendrá vigente durante 1 año siempre que no se modifiquen las condiciones establecidas en el Certificado de Examen UE de Tipo referenciado en el Anexo. This certificate will remain in force for 1 year as long as the conditions established in the EU Type certificate referenced in the annex are not modified.	




Xavier Ruiz Peña
Managing Director, Product Conformity B.U.



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El fabricante, después de completar la documentación técnica, el procedimiento de evaluación de la conformidad y la declaración UE de conformidad puede colocar el marcado CE bajo su responsabilidad / The manufacturer, after the completion of the technical documentation, the conformity assessment procedures and the EU Declaration of conformity, may affix the CE Marking under his responsibility.

ANEXO TÉCNICO TECHNICAL ANNEX

0370- 7071-PPE/C2

I. MODELOS INCLUIDOS EN EL CERTIFICADO

REFERENCES INCLUDED IN THIS CERTIFICATE

DATOS GENERALES / GENERAL DETAILS

Nº CERTIFICADO DE EXAMEN UE DE TIPO NR. EU TYPE EXAMINATION CERTIFICATE	0370-5369-PPE/B
EMITIDO POR ISSUED BY	LGAI TECHNOLOGICAL CENTER S.A. (Organismo notificado nº 0370 / Notified Body nr. 0370).
FECHA EMISIÓN ISSUE DATE	10/03/2021
VALIDEZ HASTA VALIDITY UNTIL	10/03/2026
MARCA BRAND	MYS
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) IDENTIFICATION OF THE PPE (TYPE NUMBER)	Ref.: MV99 Filtering half mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE	FFP3 NR
DESCRIPCIÓN DESCRIPTION	MEDIA MÁSCARA FILTRANTE SIN VÁLVULA, DE TIPO PLEGABLE VERTICAL, DE 5 CAPAS, DE COLOR BLANCO, CON LAZOS DE OREJA CON GANCHO, CON ALMOHADILLA NASAL Y CLIP NASAL INTERONO. TAMAÑO: 160mm×105mm. VALVELESS FILTERING HALF MASK, VERTICAL FOLDING TYPE, 5 LAYERS, WHITE COLOUR, WITH EARLOOPS WITH HOOK, WITH NOSE BRIDGE PAD AND INTERIOR NOSE CLIP. SIZE: 160mm×105mm
INFORME DE ENSAYO TEST REPORT	PTC24011707601C-EN01 issued by Precise Testing & Certification (Guangdong) Co.,Ltd.(PTC).



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检测
TESTING
CNAS L5772

Test Report



Test Requirement:

According to the requirement of the Module C2 (SPC CE-062_EN M7 PPE) of Applus+, the test item(s) of the sample is according to the standard EN149:2001+A1:2009.

Product name: Filtering half mask

Report No.: PTC24011707601C-EN01

APPLUS +With ID number: 24/32300787

Client: Xiamen Miaoxing Technology Co.,Ltd

Client Address: 5Floor,No.333-4TongFuRoad,TongAn district ,Xiamen ,China

Manufacturer: Xiamen Miaoxing Technology Co.,Ltd

Manufacturer Address: 5Floor,No.333-4TongFuRoad,TongAn district ,Xiamen ,China

Contact: Mr.Liu

Model(s): MV99

Classification: FFP3 NR

Date of Tests: 2024.02.18~2024.02.26

Signed for and on Behalf of PTC

Prepared by: Anne

Checked by:Crystal

Approved by: Miya

Anne

Crystal

Miya



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Test Report

Report No.:PTC24011707601C-EN01

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Summary of assessment

Clause	Assessment
7.3 Visual inspection	PASS
7.5 Material	PASS
7.7 Practical performance	PASS
7.8 Finish of parts	PASS
7.9.1 Total inward leakage	PASS
7.9.2 Penetration of filter material	PASS
7.16 Breathing resistance	PASS
7.18 Demountable parts	PASS

Remark:

PASS: Comply with requirement of standard

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Test Result:

Requirement	Test Result	Conclusion
7.3 Visual inspection The visual inspection shall also include the marking and the information supplied by the manufacturer.	Comply	Pass
7.5 Material Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	No mechanical failure after undergoing the conditioning described in 8.3.1, No collapse when conditioned in accordance with 8.3.1 and 8.3.2.	Pass
7.7 Practical performance The particle filtering half mask shall undergo practical performance tests under realistic conditions.	No imperfections	Pass
7.8 Finish of parts Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs.	Pass
7.9.1 Total inward leakage For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than 25 % for FFP1, 11 % for FFP2, 5 % for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22 % for FFP1, 8 % for FFP2, 2 % for FFP3.	FFP3, Test results are shown in Annex A Table 7.9.1-A&B	Pass

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7.9.2 Penetration of filter material

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤ 20%	≤ 20%
FFP2	≤ 6%	≤ 6%
FFP3	≤ 1%	≤ 1%

FFP3 , Test
results are
shown in Annex
A Table 7.9.2.

Pass

7.16 Breathing resistance

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

FFP3. Test results
are shown in Annex
A Table 7.16.

Pass

7.18 Demountable parts

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand

Comply

Pass

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Annex A: Summarization of Test Data

Table 7.9.1-A: Inward Leakage Test Data

Test specification: EN 149:2001+A1:2009 Clause 8.5

Subject	Sample No.	Condition	Walk (%)	Head Side/side (%)	Head up/down (%)	Talk (%)	Walk (%)	Mean (%)
Lv	1	A.R	1.3	1.5	1.4	1.2	1.5	1.4
Li	2	A.R	1.1	1.4	1.1	1.6	1.3	1.3
Zhong	3	A.R	1.3	1.6	1.2	1.3	1.2	1.3
Xu	4	A.R	1.2	1.1	1.3	1.5	1.2	1.3
Ma	5	A.R	0.9	1.4	1.7	1.6	1.1	1.3
Chen	6	T.C	1.3	1.1	1.5	1.2	1.7	1.4
Chen	7	T.C	1.0	1.3	1.3	1.5	1.2	1.3
Zhuo	8	T.C	0.8	1.2	1.3	1.5	1.2	1.2
Chen	9	T.C	1.6	1.0	1.5	1.1	1.5	1.3
Zhang	10	T.C	1.4	1.2	1.2	0.9	1.1	1.2

Table 7.9.1-B: Facial dimension

Subject	Face Length	Face Width	Face Depth	Mouth Width
Lv	113	139	104	53
Li	120	135	112	55
Zhong	108	135	106	56
Xu	120	150	120	70
Ma	130	170	130	80
Chen	110	160	90	40
Chen	115	145	110	50
Zhuo	103	146	100	50
Chen	110	145	95	40
Zhang	144	141	101	54

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Table 7.9.2: Penetration of filter material

Test specification: EN 149:2001+A1:2009 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	0.6	Pass
		12	0.4	
		13	0.3	
	Simulated wearing treatment	14	0.1	
		15	0.7	
		16	0.2	
	Mechanical strength + Temperature conditioned	17	0.8	
		18	0.3	
		19	0.5	
Paraffin oil test	As received	20	0.4	Pass
		21	0.1	
		22	0.1	
	Simulated wearing treatment	23	0.1	
		24	0.1	
		25	0.4	
	Mechanical strength + Temperature conditioned	26	0.2	
		27	0.3	
		28	0.2	

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Table 7.16: Breathing resistance (mbar)

Test specification: EN 149:2001+A1:2009 Clause 8.9

As received	Flow Rate		29					30					31				
	Inhalation	30 l/min	0.42					0.38					0.44				
		95 l/min	1.64					1.57					1.61				
	Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			2.41	2.43	2.37	2.27	2.31	2.44	2.37	2.29	2.36	2.37	1.99	2.31	2.03	2.17	2.25
Simulated wearing treatment	Flow Rate		32					33					34				
	Inhalation	30 l/min	0.44					0.46					0.44				
		95 l/min	1.67					1.69					1.71				
	Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			2.32	2.37	2.41	2.31	2.26	2.31	2.40	2.27	2.19	2.33	2.25	2.36	2.31	2.39	2.27
Temperature conditioned	Flow Rate		35					36					37				
	Inhalation	30 l/min	0.42					0.39					0.41				
		95 l/min	1.58					1.61					1.62				
	Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			2.33	2.41	2.29	2.34	2.39	2.40	2.37	2.50	2.39	2.41	2.37	2.41	2.22	2.39	2.40
Assessment	Pass																

A: Facing directly ahead B: Facing vertically upwards C: Facing vertically downwards
D: Lying on the left side E: Lying on the right side

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Test	Uncertainty
Total inward leakage	3.8%
Penetration of filter material(NaCl)	3.5%
Penetration of filter material(Paraffin oil)	4.2%
Breathing resistance(30L/min)	5.2%
Breathing resistance(95L/min)	5.4%
Breathing resistance(160)L/min)	6.0%

Photo(s) of Sample:



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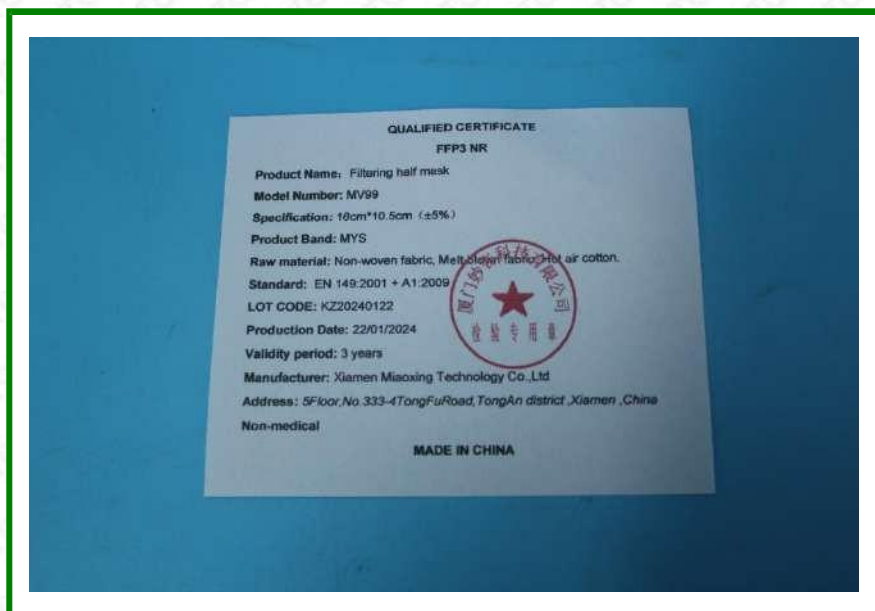


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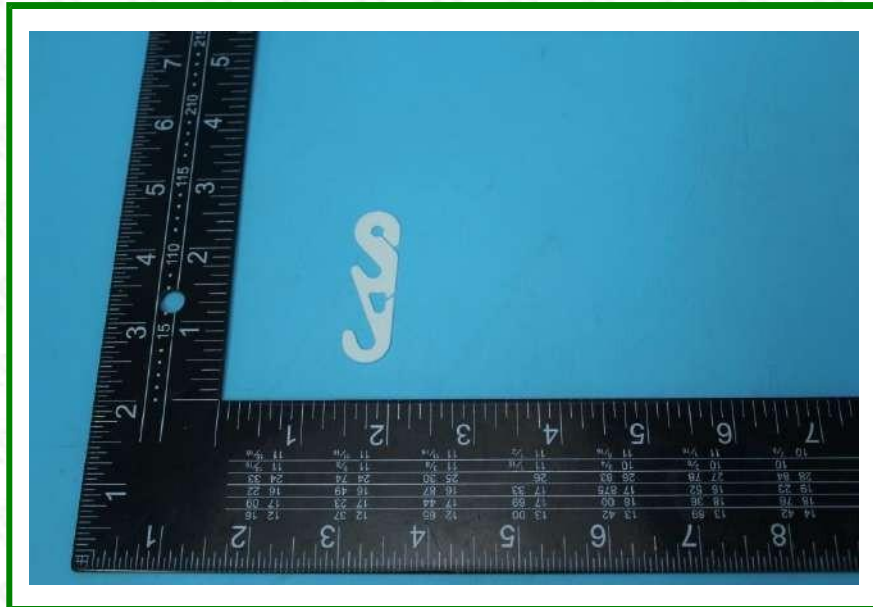


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CNAS L5772

Test Report

EN 149:2001+A1:2009 protective devices. Filtering half masks to protect against particles. Requirements, testing, marking

Product: Filtering half mask
Report No.: PTC21012905401C-EN01
Client: Xiamen Miaoxing Technology Co.,Ltd
Client Address: 5Floor,No.333-4TongFuRoad,TongAn district ,Xiamen ,China
Manufacturer: Xiamen Miaoxing Technology Co.,Ltd
Manufacturer Address: 5Floor,No.333-4TongFuRoad,TongAn district ,Xiamen ,China
Contact: Mr.Liu
Model(s): MV99
Classification: FFP3 NR
Date of Tests: 2021.02.26~2021.03.04

Signed for and on Behalf of PTC

Prepare by:

Checked by:

Approved by:

Arme

Jue

Jim Mo



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Summary of assessment

Clause	Assessment
7.3 Visual inspection	NOT TESTED
7.4 Packaging	PASS
7.5 Material	PASS
7.6 Cleaning and disinfecting	N/A
7.7 Practical performance	PASS
7.8 Finish of parts	PASS
7.9.1 Total inward leakage	PASS
7.9.2 Penetration of filter material	PASS
7.10 Compatibility with skin	PASS
7.11 Flammability	PASS
7.12 Carbon dioxide content of the inhalation air	PASS
7.13 Head harness	PASS
7.14 Field of vision	PASS
7.15 Exhalation valve	N/A
7.16 Breathing resistance	PASS
7.17 Clogging	N/A
7.18 Demountable parts	PASS
9 Marking	NOT TESTED

Remark:

PASS: comply with requirement of standard

N/A: not application

NOT TESTED: the clause were not required

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Test Result:

Requirement	Test Result	Conclusion
7.3 Visual inspection The visual inspection shall also include the marking and the information supplied by the manufacturer.	Not tested	Not tested
7.4 Packaging Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	In accordance with the requirement.	Pass
7.5 Material Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	No mechanical failure after undergoing the conditioning described in 8.3.1, No collapse when conditioned in accordance with 8.3.1 and 8.3.2.	Pass
7.6 Cleaning and disinfecting If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.	Single shift use only	N/A
7.7 Practical performance The particle filtering half mask shall undergo practical performance tests under realistic conditions	No imperfections	Pass
7.8 Finish of parts Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs.	Pass

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7.9.1 Total inward leakage

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than 25 % for FFP1, 11 % for FFP2, 5 % for FFP3

and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22 % for FFP1, 8 % for FFP2, 2 % for FFP3.

FFP3, Test results are shown in Annex A Table 7.9.1-A&B

Pass

7.9.2 Penetration of filter material

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤ 20%	≤ 20%
FFP2	≤ 6%	≤ 6%
FFP3	≤ 1%	≤ 1%

FFP3, Test results are shown in Annex A Table 7.9.2.

Pass

7.10 Compatibility with skin

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

No irritation or any other adverse effect to health.

Pass

7.11 Flammability

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

Test results are shown in Annex A Table 7.11.

Pass

7.12 Carbon dioxide content of the inhalation air

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)

Test results are shown in Annex A Table 7.12.

Pass

7.13 Head harness

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

Head harness can be donned and removed easily, adjustable or self-adjusting and

Pass

The head harness shall be adjustable or self-adjusting and shall be

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sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

have sufficiently robust to hold the particle filtering half mask firmly.

7.14 Field of vision

The field of vision is acceptable if determined so in practical performance tests.

Pass the practical performance tests.

Pass

7.15 Exhalation valve

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.

No exhalation valve

N/A

Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

7.16 Breathing resistance

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

FFP3. Test results are shown in Annex A Table 7.16.

Pass

7.17 Clogging

7.17.2 Breathing resistance

Valved particle filtering half masks:

After clogging the inhalation resistances shall not exceed:

FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow

The exhalation resistance shall not exceed 3 mbar at 160 L/min

Single shift use only.

N/A

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continuous flow

Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed:

FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow

7.17.3 Penetration of filter material

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤ 20%	≤ 20%
FFP2	≤ 6%	≤ 6%
FFP3	≤ 1%	≤ 1%

7.18 Demountable parts

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand

Comply

Pass

9 Marking

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.1.2 Type-identifying marking.

9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable.

Example: FFP2 R D.

9.1.4 The number and year of publication of this European Standard.

9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.

9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using

Not tested

Not tested

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the pictogram as shown in Figure 12b.

9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.

9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.

9.2 Particle filtering half mask

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space.

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

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Annex A: Summarization of Test Data

Table 7.9.1-A: Inward Leakage Test Data

Test specification: EN 149:2001+A1:2009 Clause 8.5

Subject	Sample No.	Condition	Walk (%)	Head Side/side (%)	Head up/down (%)	Talk (%)	Walk (%)	Mean (%)
Lv	1	A.R	1.2	1.4	1.6	1.2	1.2	1.3
Li	2	A.R	1.2	1.3	1.4	1.4	1.5	1.4
Zhong	3	A.R	1.1	1.4	1.6	1.5	1.1	1.3
Xu	4	A.R	1.3	1.3	1.4	1.2	1.2	1.3
Ma	5	A.R	1.4	1.9	1.8	1.6	1.2	1.6
Chen	6	T.C	1.2	1.7	1.7	1.5	1.5	1.5
Chen	7	T.C	1.2	1.5	1.5	1.7	1.0	1.4
Zhuo	8	T.C	1.0	1.5	1.2	1.5	1.2	1.3
Chen	9	T.C	1.5	1.5	1.5	1.7	1.7	1.6
Zhang	10	T.C	1.1	1.7	1.9	1.3	1.4	1.5

Table 7.9.1-B: Facial dimension

Subject	Face Length	Face Width	Face Depth	Mouth Width
Lv	113	139	104	53
Li	120	135	112	55
Zhong	108	135	106	56
Xu	120	150	120	70
Ma	130	170	130	80
Chen	110	160	90	40
Chen	115	145	110	50
Zhuo	103	146	100	50
Chen	110	145	95	40
Zhang	144	141	101	54

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Table 7.9.2: Penetration of filter material

Test specification: EN 149:2001+A1:2009 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	0.1	Pass
		12	0.1	
		13	0.1	
	Simulated wearing treatment	14	0.4	
		15	0.5	
		16	0.1	
	Mechanical strength + Temperature conditioned	17	0.1	
		18	0.2	
		19	0.4	
Paraffin oil test	As received	20	0.1	
		21	0.1	
		22	0.1	
	Simulated wearing treatment	23	0.2	
		24	0.2	
		25	0.2	
	Mechanical strength + Temperature conditioned	26	0.1	
		27	0.1	
		28	0.1	

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Table 7.11: Flammability

Test specification: EN 149:2001+A1:2009 Clause 8.6

Condition	Sample No.	Result	Assessment
As received	29	No burn	Pass
	30	No burn	
Temperature conditioned	31	No burn	
	32	No burn	

Table 7.12: Carbon dioxide content of the inhalation air

Test specification: EN 149:2001+A1:2009 Clause 8.7

Condition	Sample No.	Result (%)		Assessment
As received	33	0.05	Mean value: 0.05	Pass
	34	0.05		
	35	0.04		

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Table 7.16: Breathing resistance (mbar)

Test specification: EN 149:2001+A1:2009 Clause 8.9

As received	Flow Rate		36					37					38				
	Inhalation	30 l/min	0.36					0.37					0.35				
		95 l/min	1.29					1.33					1.30				
	Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			1.85	1.89	1.84	1.90	1.88	1.80	1.80	1.79	1.83	1.83	1.78	1.77	1.75	1.77	1.79
Simulated wearing treatment	Flow Rate		39					40					41				
	Inhalation	30 l/min	0.40					0.40					0.40				
		95 l/min	1.43					1.45					1.47				
	Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			2.02	2.03	2.00	2.07	2.03	2.04	2.05	2.04	2.05	2.00	2.06	2.06	2.05	2.03	2.04
Temperature conditioned	Flow Rate		42					43					44				
	Inhalation	30 l/min	0.33					0.33					0.34				
		95 l/min	1.18					1.22					1.12				
	Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			1.82	1.89	1.84	1.89	1.85	1.83	1.84	1.82	1.81	1.85	1.88	1.86	1.83	1.83	1.82
Assessment	Pass																

A: Facing directly ahead B: Facing vertically upwards C: Facing vertically downwards

D: Lying on the left side E: Lying on the right side

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Test Report

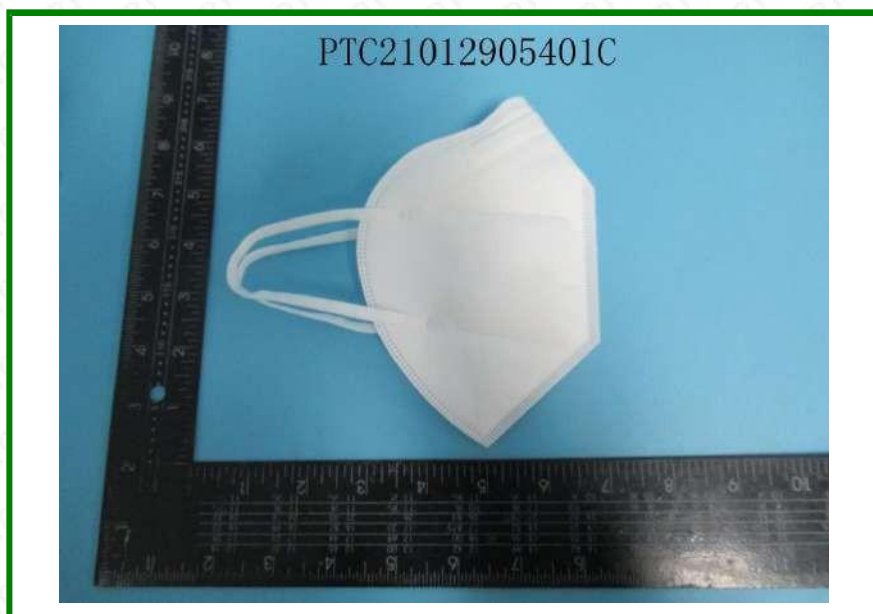
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Test	Uncertainty
Total inward leakage	3.8%
Penetration of filter material(NaCl)	3.5%
Penetration of filter material(Paraffin oil)	4.2%
Carbon dioxide content of the inhalation air	4.5%
Breathing resistance(30L/min)	5.2%
Breathing resistance(95L/min)	5.4%
Breathing resistance(160)L/min)	6.0%

Photo(s) of Sample:



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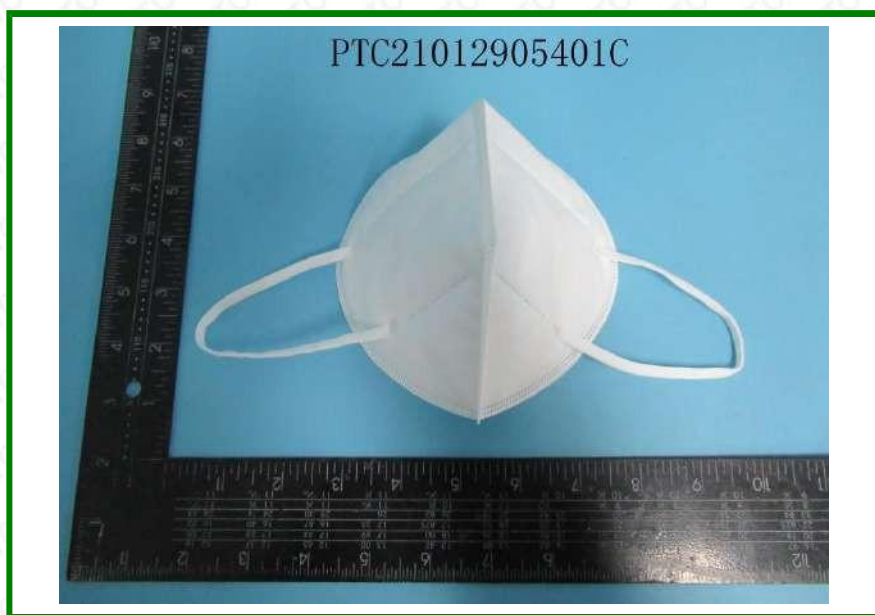


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MV99

20240316

20270315

LOT

KZ20240316

Xiamen Miaoxing Technology Co., Ltd

China

ADDRESS: 5Floor, No.333-4TongFuRd
WWW.XMMIAOXING.COM

IMPORTER: PIZZOCRI SRL
ADDRESS: VIA FONDO AUSA
C.O.E. SM29433
PHONE: 0039 0549/910442
www.pizzocri.com

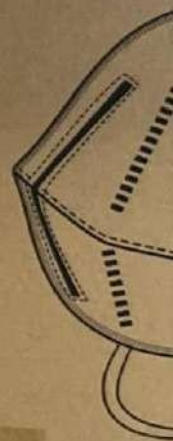


FFP3 NR

EN 149:2001+A1:2009
PPE REGULATION EU

2000 pcs

CE 0370



6/425

XYLS

FFP3 NR

EN 149:2001+A1:2009

PPE REGULATION EU 2016/4

2000 pcs

Technology Co.,Ltd

road,TongAn district, Xiamen,China

AN MARINO 47891

0





FFP3 NR

EN 149:2001+A1:2009

PPE REGULATION EU 2016/4

2000 pcs

g Technology Co.,Ltd

FuRoad,TongAn district, Xiamen,China

, SAN MARINO 47891





FFP3 NR

EN 149:2001+A1:2009

PPE REGULATION EU 2010

2000 pcs

ing Technology Co.,Ltd

ongFuRoad,TongAn district, Xiamen,China

A 28, SAN MARINO 47891

370





50
PCS

Filter 99%
particulate matter



Nasal Regulator
Perfect fitting
nose pad

Effective Filtering
Filter 96%
of particles

CE 0370

NON-MEDICAL USAGE
FOR SINGLE USE ONLY
FOR USE AGAINST NOISE AND DUST

FILTERING HALF MASK

FFP3 NR

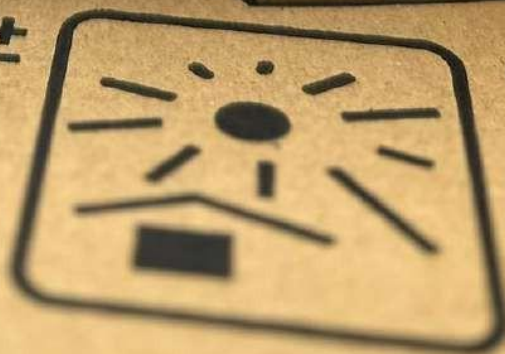
AYS

Model: MV99



EN 140:2001+A1:2009
TYPE REGULATION EU 2016/425

CE 0370





**Caratteristiche:**

Facciale filtrante a 5 strati
Materiale in TNT di alta qualità e biocompatibile
Design del nasello deformabile e degli elastici confortevole
Elastici Auricolari
Senza valvola
Protezione contro le microparticelle aeree da polveri ed inquinamento
Leggera, Traspirante, Ipoallergenica, ad alta Efficienza Filtrante

Specifiche di prodotto:

Colore: Bianco
Dimensioni: 159,99 mm x 104,44 mm
Materiali: Tessuto non tessuto
Standard: EN149:2001+A1:2009
Classe di Protezione: FFP3 NR
DPI cat. III secondo normativa EU 2016/425

Istruzioni per indossare la mascherina:

1. Rimuovere la mascherina dalla confezione, aprire e controllare se in buone condizioni. Metti la mascherina sul mento. La clip al naso dovrebbe essere posizionata in alto.
2. Posizionare gli elastici dietro le orecchie
3. Posizionare le dita tra la punta del naso e premi verso l'interno mentre muovi la punta delle dita lungo la clip per il naso finché la clip per il naso non viene premuta nella forma del ponte nasale per garantire che la mascherina sia indossata correttamente. Effettuare un controllo della tenuta dell'utente prima di utilizzare ciascun indumento. Se ci sono perdite d'aria intorno al naso o ai bordi della mascherina, regolare la clip per il naso o la posizione della mascherina.

Attenzione:

1. Questo prodotto è monouso.
2. Questo prodotto è progettato per resistere a particelle provenienti dall'atmosfera ambiente, è passato dalla norma EN149:2001 per dimostrare la conformità alla norma EHSR del regolamento (EU)2016/425.
3. Questo prodotto non è indicato per un uso prolungato nel tempo.
In caso di uso continuo del dispositivo, si consiglia di non eccedere mai le 4 ore.
4. Una mascherina danneggiata, graffiata, strappata o macchiata deve essere sostituita immediatamente.

Condizioni di conservazione:

La mascherina sigillata nel proprio confezionamento singolo deve essere tenuta in un luogo fresco ed asciutto, lontano da fonti di luce diretta. Nel caso di apertura del confezionamento singolo, tenere la bustina chiusa finché non la si indossa.
Vita utile del prodotto: 3 Anni

**Xiamen Miaoxing Technology Co.,Ltd**

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Phone: 0039 0549/910442



20240316



20270315



KZ20240316



0 6 9 7 5 8 8 4 1 1 0 1 5 9



MADE IN CHINA

**Caractéristiques:**

- Structure de filtre à 5 couches
- Sans vanne
- Matériau TNT biocompatible et de haute qualité.
- Plaquette nasale déformable et conception élastique confortable.
- Protection contre les microparticules présentes dans l'air provenant de la poussière et de la pollution.
- Léger, respirant, hypoallergénique, à haute efficacité filtrante.

Spécifications du produit:

- Couleur blanche
- Dimensions : 159,99 mm x 104,44 mm
- Matériaux : Tissu non tissé
- Norme : EN149:2001+A1:2009
- Classe de protection : FFP3 NR
- EPI Cat.III selon le Règlement (UE) 2016/425

Mode d'emploi du masque:

1. Sortez le masque de l'emballage, ouvrez-le et vérifiez s'il est en bon état. Placez le masque sur votre menton. Le pince-nez doit être placé haut.
2. Passez les élastiques derrière vos oreilles.
3. Placez vos doigts entre le bout de votre nez et appuyez vers l'intérieur tout en déplaçant le bout de vos doigts le long du pince-nez jusqu'à ce que le pince-nez soit enfoncé dans la forme de l'arête du nez pour garantir que le masque est porté correctement. Effectuer un contrôle d'étanchéité sur l'utilisateur avant d'utiliser chaque vêtement. Si de l'air fuit autour du nez ou des bords du masque, ajustez le pince-nez ou la position du masque.

Attention:

1. Ce produit est jetable.
 2. Ce produit est conçu pour résister aux particules de l'atmosphère ambiante, il a passé la norme EN149:2001 pour démontrer sa conformité à la norme EHSR du règlement (UE) 2016/425.
 3. Ce produit ne convient pas à une utilisation à long terme.
- En cas d'utilisation continue de l'appareil, il est recommandé de ne jamais dépasser 4 heures.

4. Une façade endommagée, rayée, cassée ou tachée doit être remplacée immédiatement.

Conditions de stockage:

Le masque scellé dans son emballage individuel doit être conservé dans un endroit frais et sec à l'abri des sources de lumière directe. Si vous ouvrez l'emballage individuel, gardez l'enveloppe fermée jusqu'à ce que vous la mettiez.

Durée de vie du produit : 3 ans

**Eigenschaften:**

- 5-lagiger Filteraufbau
- Hochwertiges und biokompatibles TNT-Material
- Verformbares Nasenpolster und komfortables elastisches Design
- Ohne Ventil
- Schutz vor Mikropartikeln in der Luft durch Staub und Verschmutzung
- Leicht, atmungsaktiv, hypoallergen, mit hoher Filtereffizienz

Produktspezifikationen:

- weiße Farbe
- Abmessungen: 159,99 mm x 104,44 mm
- Materialien: Vliesstoff
- Norm: EN149:2001+A1:2009
- Schutzklasse: FFP3 NR
- PSA-Kat. III gemäß EU-Verordnung 2016/425

Anleitung zum Tragen der Maske:

1. Nehmen Sie die Maske aus der Verpackung, öffnen Sie sie und prüfen Sie, ob sie in gutem Zustand ist. Legen Sie die Maske auf Ihr Kinn. Der Nasenclip sollte hoch positioniert sein.
2. Platzieren Sie die Gummibänder hinter Ihren Ohren.
3. Legen Sie Ihre Finger zwischen die Nasenspitze und drücken Sie sie nach innen, während Sie Ihre Fingerspitzen entlang des Nasenbügels bewegen, bis der Nasenbügel in die Form des Nasenrückens gedrückt wird, um sicherzustellen, dass die Maske richtig getragen wird. Führen Sie vor der Verwendung jedes Kleidungsstücks eine Passformprüfung durch. Wenn rund um die Nase oder an den Rändern der Maske Luft austritt, passen Sie den Nasenclip oder die Position der Maske an.

1. Dieses Produkt ist Einwegartikel.
2. Dieses Produkt ist so konzipiert, dass es Partikeln aus der Umgebungsluft widersteht. Es hat die Norm EN149:2001 bestanden, um die Einhaltung der EHSR-Norm der Verordnung (EU) 2016/425 nachzuweisen.
3. Dieses Produkt ist nicht für den längeren Gebrauch geeignet.

Bei kontinuierlicher Nutzung des Geräts wird empfohlen, die Dauer von 4 Stunden nie zu überschreiten.

4. Eine beschädigte, zerkratzte, eingerissene oder fleckige Maske muss sofort ersetzt werden.

Lagerbedingungen:

Die in der Einzelverpackung versiegelte Maske muss an einem kühlen, trockenen Ort und fern von direkten Lichtquellen aufbewahrt werden. Wenn Sie die Einzelverpackung öffnen, halten Sie den Beutel geschlossen, bis Sie ihn aufsetzen.

Nutzungsdauer des Produkts: 3 Jahre

Color:



**Features:**

- Five-layer Filtering Structure.
- High-quality and Skin-friendly Non-woven Materials.
- Comfortable Nose Bridge.
- Without Breathing Valve.
- Ear elastics
- Protections against Air-born Particles, Pollutants, Dusts, etc.
- Light-weight, Breathable, Hypoallergenic, High-filtration-efficiency

Specifications:

- Color: White
- Dimension: 159.99mm x 104.44mm
- Materials: Polypropylene fiber products, Non-woven fabric
- Standard: EN149:2001+A1:2009
- Protection Class: FFP3 NR
- PPE cat. III acc. to EU 2016/425

Fitting Instructions:

1. Remove the mask from the package, open and check if in good condition. Place the mask on your chin. The nose clip should be positioned high.
2. Place the elastic bands behind your ears
3. Place your fingers between the tip of your nose and press inward as you move your fingertips along the nose clip until the nose clip is pressed into the shape of the nose bridge to ensure the mask is worn correctly. Conduct a user fit check before using each garment. If there is air leakage around the nose or edges of the mask, adjust the nose clip or the position of the mask.

Warning:

1. This product is disposable.
2. This product is designed to against particles from the ambient atmosphere, it has passed EN149:2001 to show conformity to the EHSR of Regulation (EU) 2016/425.
3. This product is not intended for long term use. A period of continuous wearing of no more than 4 hours is recommended.
4. Spotted, scratched or damaged mask should be replaced immediately.

Instructions for removing and disposing of the respirator:

1. Do not touch the front of the respirator. The front side is contaminated. Only touch the rubber bands. Remove the respirator by pulling on the lower and then the upper rubber band.
 2. Throw the used respirator in a waste receptacle. Follow local regulations for disposing of waste. Prevent the risk of contamination and spread of any potential infection.
 3. Wash your hands with soap and water, dry them and use hand sanitizer.
- Single-use protective equipment should only be used once and then thrown in the trash. The respirator must be replaced if it is damp, contamination has passed through the respirator or respiratory resistance has increased.

Storage:

The mask with sealed packaging should be stored in a cool & dry place, and away from direct sunshine. Please seal the mouth of bag timely after opening.

Shelf Life: 3 Years

**Características:**

- Estructura de filtro de 5 capas
- Material TNT biocompatible y de alta calidad
- Sin válvula
- Almohadilla nasal deformable y cómodo diseño elástico.
- Protección contra micropartículas en el aire provenientes del polvo y la contaminación.
- Livianas, transpirable, hipoalergénico, con alta eficacia filtrante.

Especificaciones del producto:

- Color blanco
- Dimensiones: 159,99 mm x 104,44 mm
- Materiales: Tela no tejida
- Estándar: EN149:2001+A1:2009
- Clase de protección: FFP3 NR
- EPI Cat. III según el Reglamento (UE) 2016/425

Instrucciones para usar la mascarilla:

1. Saque la mascarilla del paquete, ábrala y compruebe si está en buenas condiciones. Coloque la mascarilla en tu barbilla. La pinza nasal debe colocarse en alto.
2. Pase las gomas por detrás de sus orejas.
3. Coloque los dedos entre la punta de la nariz y presione hacia adentro mientras mueve las puntas de los dedos a lo largo del clip nasal hasta que el clip nasal quede presionado en la forma del puente nasal para garantizar que la mascarilla se use correctamente. Realizar un control de sellado del usuario antes de usar cada prenda. Si hay fugas de aire alrededor de la nariz o los bordes de la mascarilla, ajuste la pinza nasal o la posición de la mascarilla.

Atención:

1. Este producto es desechable.
 2. Este producto está diseñado para resistir partículas de la atmósfera ambiental, ha pasado la norma EN149:2001 para demostrar el cumplimiento de la norma EHSR del Reglamento (UE) 2016/425.
 3. Este producto no es apto para uso prolongado. En caso de uso continuo del dispositivo, se recomienda no exceder nunca las 4 horas.
 4. Una placa frontal dañada, rayada, rota o manchada debe reemplazarse inmediatamente.
- Condiciones de almacenaje:
La mascarilla precintada en su embalaje individual debe conservarse en un lugar fresco, seco y alejado de fuentes de luz directa. En caso de abrir el envase individual, mantener el sobre cerrado hasta el momento de ponérselo.
- Vida útil del producto: 3 Años

FFP3 NR

EN 149:2001+A1:2009

PPE REGULATION EU 2016/425

2000 pcs

CE 0370





XYG

FFP3

EN 149:2001+A1

PPE REGULATIONS

2000 pieces

Technology Co.,Ltd

FuRoad,TongAn district

, SAN M

370





Technology Co.,Ltd

ad,Ten en,China

FFP3 NR

EN 149:2001+A1:2009

PPE REGULATION EU

2000 pcs

CE 0370





【PRODUCT ITEM】 FILTERING HALF MASK

【SIZE】 16*10.5 CM ($\pm 5\%$)

【QTY】 2000 PCS - 40 BOXES OF 50 PIECES

【G.W】 17,00KGS

【N.W】 16,50KGS

【MEAS】 69*55.5*39.5CM



0 6 9 7 5 8 8 4 1 1 0 1 5 9

MADE IN CHINA

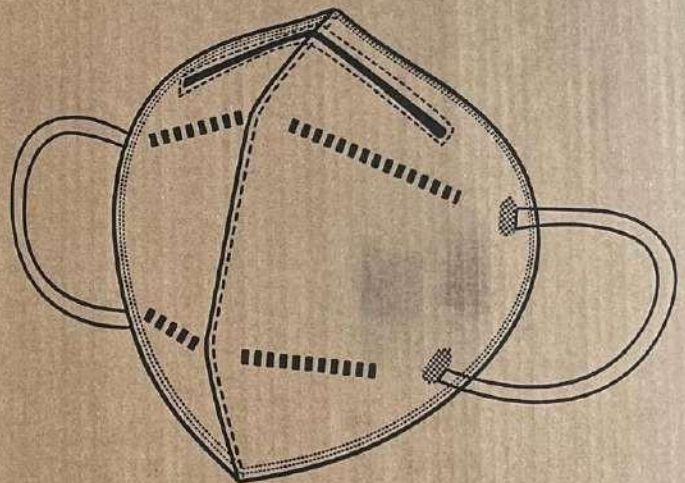
FFP3 NR

EN 149:2001+A1:2009

PPE REGULATION EU 2016/425

2000 pcs

CE 0370



REF

MV99



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KZ20240316



Xiamen Miaoxing Technology Co.,Ltd

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WWW.XMMIAOXING.COM

IMPORTER: PIZZOCRI SRL
ADDRESS: VIA FONDO AUSA 28, SAN MARINO 47891
C.O.E. SM29433
PHONE: 0039 0549/910442
www.pizzocri.com



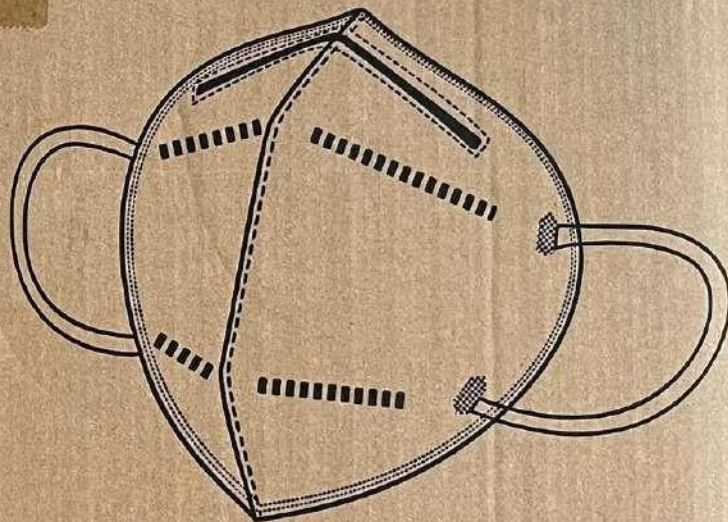
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EN 149:2001+A1:2009

PPE REGULATION EU 2016/425

2000 pcs

CE 0370



ATTESTAZIONE DI VERIFICA E REGISTRAZIONE CONTABILE

relativa alla DELIBERAZIONE DEL DIRETTORE GENERALE con oggetto:

**PROCEDURA APERTA PER LA FORNITURA ANNUALE DI MASCHERINE CHIRURGICHE, FACCIALI
FILTRANTI FFP2 E FFP3 (DET. D.G. SO.RE.SA. N. 227-2024) - ADESIONE AZIENDALE**

ATTESTAZIONE DI VERIFICA E REGISTRAZIONE CONTABILE 1 (per le proposte che determinano un costo per l'AORN)

Il costo derivante dal presente atto : €4.704,00

- è di competenza dell'esercizio 2025 , imputabile al conto economico 5010107010 - Dispositivi Medici
da scomputare dal preventivo di spesa 6/12 che presenta la necessaria disponibilità
- è relativo ad acquisizione cespiti di cui alla Fonte di Finanziamento

ATTESTAZIONE DI VERIFICA E REGISTRAZIONE CONTABILE 2 (per le proposte che determinano un costo per l'AORN)

Il costo derivante dal presente atto : €4.704,00

- è di competenza dell'esercizio 2026 , imputabile al conto economico 5010107010 - Dispositivi Medici
da scomputare dal preventivo di spesa 6/12 che presenta la necessaria disponibilità
- è relativo ad acquisizione cespiti di cui alla Fonte di Finanziamento

Caserta li, 30/06/2025

il Direttore
UOC GESTIONE ECONOMICO FINANZIARIA
Carmela Zito