



Delivering innovative solutions
for older adults at a PIVOTAL
time of their lives

COVID-19 Pandemic
Canada
April 2020

Personal Protective Equipment
NK-95 FFP2 FFP3

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North American Importers

Niagara-On-The-Lake
Ontario



FFP3

Understanding the difference.

Getting the right protection.

MASK, RESPIRATOR, SURGICAL, N-95, NK-95, FFP2, FFP3

READ the full report:

<https://fastlifehacks.com/n95-vs-ffp/>

Opinions expressed in this report are that of the author. It has been included as a point of research and basic understanding.



Mask vs Respirator

N95 (95%) = FFP2 / P2 (94%)



N99 (99%) = FFP3 (99%)

N100 (99.97%) = P3 (99.95%)



Valve vs Non-Valved



Valved respirators make it easier to exhale air. This makes them more comfortable to wear, and leads to less moisture build-up inside the respirator. Ideal for things like DIY/construction work.



The problem with valved respirators is that they **do not** filter the wearer's exhalation, only the inhale. This one-way protection puts others around the wearer at risk, in a situation like Covid-19. It's for this reason that hospitals and other medical practices **do not** use valved respirators.



Product:
Respirator Face Mask

Type:

KN95

Layers:

4

%:

95%



**KN95 FFP2 4 layer
Respirator Face Mask**

Prices start at
\$3.65 CAD

KN95

EN 149:2001 + A1:2009

GB2626=2006 KN95

Approved by:

Ministry of Health - Netherlands/China

Production:

14+/- working days*



Agent:

Netherlands Institute of Healthcare and Wellbeing B.V. (NIHW),
KVK 61374288. +31 88 605 6260, b.stam@nihw.org



Product:

Respirator Face Mask

Type:

FFP3

Layers:

6

%:

99.9%

**FFP3 6 layer
Respirator Face Mask**

FFP3

EN 149:2001 + A1:2009

GB2626=2006 KN95

Approved by:

Ministry of Health - Netherlands/China

Production:

14+/- working days*



Agent:

Netherlands Institute of Healthcare and Wellbeing B.V. (NIHW),
KVK 61374288. +31 88 605 6260, b.stam@nihw.org

Manufactured: KN95 FFP3

China



Eindbeoordelingsformulier

Datum	7-9
Inkoopnummer	
Lotsnummer	X038
Leverancier	
Productnaam of naam fabrikant	
Productiedatum	
Type mondkap (volgens de fabrikant)	

Goedkeuring RVM	+	+/-	-
Goedkeuring AH/TOX	+		
Algemene bevindingen:			

Particle Penetration	Testgemiddelde
Algemene bevindingen:	99.97% 8

	FF Pass Level	
	Zonder clip	Met clip
Test 1	164	
Test 2	125	
Gemiddelde 3	14 (niet gesloten)	
FFP2 (Ja/Nee)		

Versturen (JA/NEEN/ONHOLD)	aanvragen! FFP3 zoveel mogelijk aanvragen.
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Artikelnummer VWS:	
Algemene bevindingen:	

Added level of inspection:

Both products are certified from China however there are always concerns over potentially fraudulent or non-performing products.

Buyers have the option of simply accepting the order with manufacture's certification or allowing our partners in the Netherlands (NIHW) a few additional days to perform an independent test. Once the product is confirmed to meet specifications, the order is ready to be cleared.

SEE NIHW company profile and report detailing (following pages).



Factory production:

Up to 500,000 units per day*

Minimum order 60,000 units

*Production rates and time is dependent on supply and demand and COVID-19 related pressures. Although production times are quoted, changes may occur.

Packaging:

Masks are packaged and palletted ready for shipping. Certification and PPF3/KN95 PPF2 identification.

Prices are quoted CAD - FOB Factory in China. Pre-paid. Prices may change due to costs and global pressures.

Prices quoted do not include: FOB Toronto Airport, all taxes, shipping, freight, insurance, landed transport, customs and tariffs.



NIHW Letter on Product Testing and Quality Assurance

To whom it may concern:

NIHW is active with smart software for elderly care, used by municipalities, care institutions and the elderly / family themselves. The software suite is called Sophie and is based on interRAI algorithms, from the scientific network of approximately 80 universities worldwide with approximately 600 connected scientists.

Within the Netherlands, the software is supplied from the Netherlands Institute voor Gezondheidszorg en Welzijn (NIGW), under the trade name Mensken.

For the international activities, it is supplied from the Netherlands Institute of Healthcare & Wellbeing (NIHW). North American distribution by Pivotal Aging Innovations Inc. (Canada). NIHW Hong Kong is a shareholder of the Equity Joint Venture in China, Beijing, operating under the name Yikang Guangji Science and Technology Development Beijing Limited company (Yikang).

Corona - Extending to Personal Protective Equipment

In anticipation of the Corona crisis and the possible shortage of face masks and other protective materials for healthcare professionals, NIHW has contacted its Dutch and Chinese network partners. This started the current collaboration, delivering Personal Protective Equipment like respirators / mouth masks and others to healthcare professionals in the Netherlands.

For mouth masks, NIHW has selected several types from approximately 300 Chinese suppliers, of which 4 suppliers now have a permanent relationship.

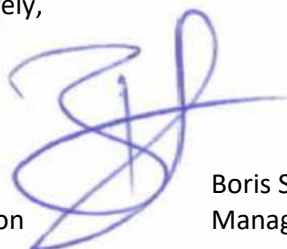
Officially tested and approved by Ministry of Health

The selected products are tested by the official Netherlands Government test laboratory located in Vianen (Netherlands) for approval. Tests are performed on the samples received per batch of produced products.

The products Duckbill Mask FFP2 and G Masks FFP2 are both tested and approved having both the FFP3 quality. For this tender, the G Mask is offered.

Should you need any further confirmation or expansion on this letter of support, please feel free to contact me directly.

Sincerely,


Name Boris Stam
Position Managing Partner NIHW



Product: Respirator Face Mask
Type: KN95, 4 layers, filtering N95 (95%): Approved FFP3 by Ministry of Health / Netherlands
Certification: CE, EC, Kalibra, ISO 13485:2016, KN95, N95, EN 149:2001+A1:2009
Origin: China
Delivery: 10-12 production days
Agent: Netherlands Institute of Healthcare and Wellbeing B.V. (NIHW)
Chamber of Commerce 61374288.
+31 88 605 6260, b.stam@nihw.org





Landesamt für Arbeitsschutz, Verbraucherschutz und Gesundheit
Abteilung Arbeitsschutz, Regionalbereich Ost | Postfach 13 45 | 15203 Frankfurt (Oder)

MILA Health Care GmbH i.G.
Herrn Michael Laschinsky
Mies-van-der-Rohe-Str. 2
D-14469 Potsdam

Per E-Mail: ml@mila-potsdam.de

Robert-Havemann-Str. 4
15236 Frankfurt (Oder)

Bearb.: Herr Bilz
Vorgangsz.: A- 6282/2020
(Bitte stets angeben)
F201700029 / 306.84

Telefon: 0331 8683-232
Telefax: 0331 27548-1803
<https://lavg.brandenburg.de/arbeitschutz>
matthias.bilz@lavg.brandenburg.de

Tram 4 (Haltestelle: Friedhof)

Frankfurt (Oder), 09.04.2020

Bestätigung der Einfuhrfähigkeit,
hier: Persönliche Schutzausrüstung (PSA) –
Schutzmasken nach chinesischer Einstufung KN95

Confirmation of importability,
here: Personal protective equipment (PPE) - protective
masks according to Chinese classification KN95

Sehr geehrter Herr Laschinsky,

Dear Mr. Laschinsky,

für die von Ihnen elektronisch vorgestellte persönliche
Schutzausrüstung (hier Schutzmaske Marke Daddybaby,
Nr. 2020326) haben sie mit einem Zertifikat der GTTC (Nr.
200053564) ein gültiges Prüfzertifikat eines akkreditierte
Prüfzentrums, bzw. in diesem Fall einer staatseigenen
Unternehmensgruppe, vorgelegt.
Die Schutzmaske der Einstufung KN95 erfüllt die
entsprechende chinesische Prüfnorm GB 2626-2006.

For the personal protective equipment you have
presented electronically (here protective mask brand
Daddybaby, No. 2020326), you have submitted a valid
test certificate from an accredited test center, or in this
case a state-owned group of companies, with a GTTC
certificate (No. 200053564).
The protective mask with the KN95 classification
complies with the corresponding Chinese test standard
GB 2626-2006.

Entsprechend der Empfehlung der Europäische
Kommission 2020/403 vom 13. März 2020 sowie des
Erlasses MÜ-2020-1 des Ministerium für Soziales,
Gesund-heit, Integration und Verbraucherschutz i.V.mit der
1. Ergänzung vom 24.03.2020, ist die Bereitstellung dieser
Produkte auf europäischen Markt (und damit die Ein-fuhr
und das Inverkehrbringen) zulässig.

According to the recommendation of the European
Commission 2020/403 of March 13, 2020 and the
decree MÜ-2020-1 of the Ministry of Social Affairs,
Health, Integration and Consumer Protection in
conjunction with the 1st supplement of March 24, 2020,
the provision of these products permitted on the
European market (and thus the import and the placing
on the market).

Freundliche Grüße
Im Auftrag
Bilz

Kind regards
On behalf
Bilz



Annex A: Test conducted by the government of The Netherlands

Passed 100% particle resistance, tested with FFP3 qualification;

Lot Number: X059 – for verification please contact corona-advies@cb.nl

Eindbeoordelingsformulier X en Z			
FFP mondmaskers			
Datum	X059		
Nummer	15-4-2020		
Terugkoppelen aan	100		
Mailadres			
Productnaam of naam fabrikant	Dingeman (afzet desk)		
Productiedatum			
Type mondmasker (volgens de fabrikant)	FFP3		

	+	+/-	-
Oordeel RIVM			
Oordeel AH/TOXI			
Algemene bevindingen:			

Particle Penetration	Testgemiddelde
0,3	
0,5	
Algemene bevindingen: 100%	

Fit test	Zonder clip	Met clip
Test 1		
Test 2		
Test 3		
FFP-2 Pass level (Ja/Nee)		
Algemene bevindingen: not.		




Aankopen
<input checked="" type="checkbox"/> JA
<input checked="" type="checkbox"/> NEE
Type masker:
Algemene bevindingen: marcel vragan, aankopen voldoet wel aan FFP3 maar



Annex B: EC Certificate

Document has been anonymized for buyer confirmation;

Original document will be made available to the buyer after order confirmation;

 EC Certificate Directive 93/42/EEC Annex V Production Quality Assurance Medical Devices	
Registration No.:	
Report No.:	
Manufacturer:	
Products:	Aspects of manufacture concerned with securing and maintaining sterile conditions of Sterile Surgical Drapes, Sterile Surgical Gowns, Sterile Disposable Surgical Procedure Packs, Medical Face Masks Replaces Approval, Registration No.:
Expiry Date:	2022-07-29
<p>The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.</p>	
Effective Date:	2019-02-28
Date:	2019-02-28
 Notified Body  Dr. H. Lüdemann	
TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.	

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Annex C: EN ISO 13485:2016 certification

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 TÜVRheinland	
<h1>Certificate</h1>	
The Certification Body of TÜV Rheinland LGA Products GmbH	
hereby certifies that the organization	
<div style="border: 1px solid black; height: 100px; width: 100%;"></div>	
has established and applies a quality management system for medical devices for the following scope:	
(see attachment for scope)	
Proof has been furnished that the requirements specified in	
EN ISO 13485:2016	
are fulfilled. The quality management system is subject to yearly surveillance.	
Effective Date:	2019-02-28
Certificate Registration No.:	
An audit was performed. Report No.:	
This Certificate is valid until:	2020-07-06
Certification Body	
 Deutsche Akkreditierungsstelle D-ZM-14169-01-02	  Dr. H. Lüdemann
Date 2019-02-28	
TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg Tel.: +49 221 306-1371 Fax: +49 221 806-3935 e-mail: cert-validity@tuv.com http://www.tuv.com/safety	

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Annex D: Certificate of Conformity

Document has been anonymized for buyer confirmation;

Original document will be made available to the buyer after order confirmation;

	
<h3>Certificate of Conformity</h3>	
Certification No:	
Applicant:	
Address:	
Manufacturer:	
Address:	
Certification Marking:	CE-PPE
Product Description:	Disposable Protective Face Mask
Model:	VM-01
Sufficient samples of the product have been tested and found to be in conformity with	
Test Standards	: EN 149:2001+A1:2009
When tested as specified, the submitted sample complies with Personal Protective Equipment (PPE) – Regulation (EU) 2016/425	
The certificate is based on a single evaluation of one sample of above-mentioned products. It does not imply an assessment of the whole production and does not permit the use of the test laboratory logo.	
	 Authorized Signer:  Mar 19, 2020
Oct Technology Testing Co., Ltd. 637, No. 56, Zhongyun Road, Panyu District, Guangzhou, Guangdong Province, China TEL: 020-89015652, 888@oucetesting.com, www.oucetesting.com	