

This sheet is the cover sheet for all subsequent sheets having the same document number. The revision index and a brief description of the revision shall be entered on the cover sheet. The last revision index shall be added to the document number on the cover sheet an equally applies to all sheets having that document number. The new revision index is shown on all sheets.

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Free Area for Client Logo and Data



**OIM for Filtering Mask,
Daddy's Choice T0001™ FFP2 NR
3410-T1-9998
www.daddys-choise.de**
sales@daddys-choise.de

**YHH
GmbH**

Product	Daddy's Choice Purism
Type	FFP2 NR
Standard	149:2009:2001
Component	3410-T1-9998 - DC T0001 FFP2 NR - Mask
Eng.Serv.-No.	
Eng.Serv.-Title	

Original Size	A 4
Scale	1:1
DCC	Basis document
DG	GEN

QM & OIM (Operating Instruction Manual)
Product documentation for the Filtering Mask "DC T0001"
General design for FFP2 Mask according EU Standard
EN149:2001+A1:2009 FFP2 NR

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1 Operation & maintenance manuals & instructions- Process

1.1 About this manual

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1.1.1 Purpose and scope

Particle Filtering Half Mask, FFP2 Mask, according EU Standard EN149:2001+A1:2009 FFP2 NR.

1.1.2 Presentation conventions

PPE Regulation EU 2016/425 Category III

1.1.3 Safety and warning symbols

DANGER	DANGER indicates a hazard with a high level of risk which, if not avoided, will result in death or serious injury.
WARNING	WARNING indicates a hazard with a medium level of risk which, if not avoided, could result in death or serious injury.
CAUTION	CAUTION indicates a hazard with a low level of risk which, if not avoided, could result in minor or moderate injury.

1.2 Description of product

1.2.1 General information

Mask according EU Standard “EN 149 - Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking.

This European Standard specifies the minimum requirements for filtering half masks used as respiratory protective devices, specifically against particles, and the required laboratory and practical performance tests to assess masks’ compliance. Half masks used for escape purposes are excluded from the scope of this standard.

A filtering half mask is one in which the facepiece consists entirely or substantially of filter material or comprises a facepiece in which the main filter(s) form an inseparable part of the device.

Under the preceding EN149:1991 standard, the classifications were FFP1S, FFP2S, FFP2SL, FFP3S and FFP3SL. EN149:2001 classified half masks into three types according to their filtering capacities (e.g., FFP1, FFP2, and FFP3). Respirators that meet the requirements of EN149:2001 are designed to protect against solids, water-based aerosols, and oil-based aerosols.

EN149:2001 differs from EN149:1991 in that it is mandatory for all products tested in accordance with EN149:2001 to provide protection against solid and liquid aerosols whereas EN149:1991 allows for the testing of respirators against solid aerosols only. On 1 August 1 2010, an amendment to EN 149.2001 standard entered into force concerning the reusability of masks’ dust filters, indicated by “R”, reusable, and “NR”, non reusable, and tagged as EN 149:2001+A1:2009. The EN 149 defines the following classes of filtering half masks (i.e., respirators that are entirely or substantially constructed of filtering material):

Class APF (Assigned Protection factor) Filter penetration limit (at 95 L/min air flow) Inward leakage

FFP1: 4 Filters at least 80% of airborne particles <20%

FFP2: 10 Filters at least 94% of airborne particles <6%

FFP3: 20 Filters at least 98% of airborne particles <2%

To confirm: an FFP3 respirator mask would filter out at least 98% of the airborne respirable particles, whereas an FFP1 respirator mask would filter out at least 80% of the respirable particles. FFP3 respirator masks are, therefore, the most efficient in filtering out fine particles including viruses, mold spores, and asbestos.”

1.2.2 Design basis / Intended use

Particulate Respirator / Surgical Mask

- The Mask NR-008 is a FFP2 NR mask type, approved: EU Standard EN149:2001+A1:2009 FFP2 NR
- This health care FFP2 particulate respirator and surgical mask has comfortable inner materials and helps provide respiratory protection against certain airborne particles
- The individually packaged flat fold design allows for convenient storage prior to use
- EC cleared for use as a surgical mask
- Fluid resistant and disposable
- Adjustable Nose Clip
- Braided and stapled ear band

YHH	FFP2 NR Mask
Manufacturer #	Daddy's Choice Shangdong
Brand	Daddy's Choice™ T0001
Manufacturer	Shandong Daddy's Choice Health Science and Technology Co., Ltd. Address: Tiandingfeng road Garden street Economic Development Zone Linyi County Dezhou City Shandong Province, China.
Country of Origin	China
Application	Particulate Respirator / Surgical Mask
Color	White
Fastening Type	Elastic Strap
Protection Level	FFP2 NR
Size	One Size Fits Most
Sterility	NonSterile
Style	Flat Fold
Type	Respirator
User	Adult
Quantity	64.000
Built	2020-09-18

1.2.3 Main components

1.2.4 Technical data

Kennzeichnung:

Marking:



Benannte Stelle für EU-Baumusterprüfbescheinigung nach EN149:2001+A1:2009:

Notified body for EU Type Examination certificate according (EU)2016/425 and EU standard EN149:2001+A1:2009:

Mask Model: Daddys Choice T0001, According Technical Procurement Specification

UNIVERSAL CERT/ TR (NB2163):

Yukariya Dudullu Ümraniye / Istanbul / Turkey

Module B:

Certificate No. 2163-PPE-1056;

Test report for FFP2 NR Mask: 2163-KKD-1056

Module C2:

Certificate No. 2163-PPE-1056/01;

Test report for FFP2 NR Mask: 2163-PPE-1056/01

Benannte Stelle für QM (Product Service) nach EU Directive 2016/425 for T0001 (alias Purism KN95)

Notified body for EU Type Quality Management certificate according PPE Regulation (EU) 2016/425 for T0001(alias Purism KN95):

BSI (2797)

BSI Group The Netherlands B.V.

Amsterdam / Holland

Certificate No. CE 729899 (CE BSI EU Type examination certificate)

Certificate No. CE 729900 (CE BSI ModuleC2 certificate)

TÜV Rheinland (Notified Body number: 0123),

Test Report verification of T0001 (alias Purism KN95) via TÜV Rheinland, located in Shandong, PR. China

TÜV Rheinland AG, Am Grauen Stein, 51105 Köln, Germany

Certification No.: 178140684a 001

1.2.5 Product modifications

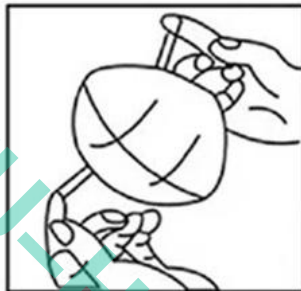
N/A

1.3 Safety

1.3.1 Instructions

As with any respiratory device, the wearer must be adequately trained prior to use. Before use, the wearer should always check the mask is in good condition, no dirt, no damage to head harness attachment etc..

WEARING A METHOD



1. Hold the mask so that the stiff bendable strip is on top



2. Pull the bottom of the face mask over your chin.



3. Hold the mask by the ear loops, and place a loop around each ear.



4. Pinch the nose strip to conform to the shape of your nose.



5. Check mask tightness before entering work area .
 • Cover your face with both hands and exhale quickly
 • If air leaks from the nose, go back to step 4
 • If air leaks from the edges, adjust the earband

1.3.2 Essential safety principles

WARNING:

1. This mask marked "NR", shall not be used for more than one shift.
2. Never substitute, modify, add, or omit parts in the configuration as specified by the manufacture.
3. This mask helps protect against certain particulate contaminants but does not completely eliminate exposure to the risk of contracting disease or infection.
4. It is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal.
5. Change the mask immediately if breathing becomes difficult or the mask becomes damaged or distorted.
6. Change the mask if a proper face seal cannot be achieved.

1.3.3 Limits of use

LIMITATION:

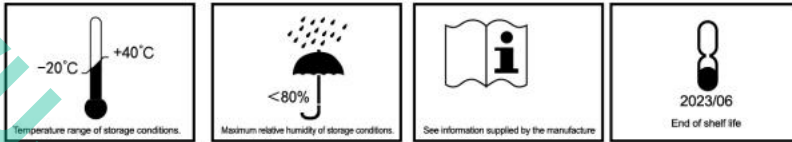
Do not use the respirator or enter or stay in a contaminated area under the following circumstances:

- a. Atmosphere contains less than 19.5% oxygen.
- b. If you smell or taste contaminant.
- c. For protection against gases or vapors.
- d. Contaminants or their concentrations are unknown or immediately dangerous to life or health.
- e. For sandblasting, paint-spray operations and asbestos treatment.
- f. In explosive atmospheres.

1.3.4 Storage

STORAGE

- 1 Store the mask in a sealed container away from contaminated areas when not use.
- 2 Store the mask in the original packing during transport.



1.3.5 Lifetime

3 years.

1.4 Maintenance

Only for one-time use.

1.5 Service and spare parts

N/A

1.6 Attachments

1.6.1 Declaration of conformity (EC)

See attachment s

1.6.2 Safety data sheets (chemicals)

See attachment s

1.6.3 Local check list

Quality monitoring report

3410-T1-1031_Rev00_MR Masks Supplier Daddys Choise Shangdong

1.6.4 Drawings

Origin Plastic Package (OPP) with instructions

See attachment s

Box for the Masks

See attachment s

Transport Carton for the Boxes

See attachment s

2 Norm and Regulation / additional attachments

2.1 Norms, Regulations, Directives

2.1.1 DIN, EN

EN149:2001+A1:2009

2.1.2 Regulation

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

2.1.3 Directives

Directive 89/686/EEC, partial

2.1.4 Auflagen Behörde / Genehmigungen / Vergleiche

- dcp-ncov, Quelle: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019> , Stand 2020-06-26
- pruefnormenvergleich-filterschutzmasken-ffp2-mit-chinesischer-norm-gb-2626-2006-kn95-berliner-feuerwehr-data.pdf, Quelle: <https://www.din.de/resource/blob/709926/90f68f9e40ad379606ad389abd9d5e55/pruefnormenvergleich-filterschutzmasken-ffp2-mit-chinesischer-norm-gb-2626-2006-kn95-berliner-feuerwehr-data.pdf>, Stand 2020-06-26
- Mask Tab "multimedia-1.pdf", Quelle: www.3m.com
- Covid19, Liste-der-Gueter (see attachment).

2.2 Declaration of Conformity

3410-T1-DC - T0001 MASK FFP2 CE_2020-09-21_signed

3 MAIN VENDOR INFORMATION OF PRODUCT

3.1 Vendor

3.1.1 Vendor/Manufacturer Info

Shandong Daddy's Choice Health Science and Technology Co., Ltd.

Address: Tiandingfeng road Garden street Economic Development Zone Linyi County Dezhou City Shandong Province, China.

TEL: 86-400-996-5015

Email: service@daddychoice.com

3.1.2 Company Registration

NA

3.1.3 Packing List

NA

3.1.4 Product Stamp and Number



3.1.5 Sub Supplier EU Declaration of Conformity

See Attachment

3.1.6 Sending Documents

See Attachment

4 Attachments

3410-T1-T0001-DC MASK FFP2 CE_YHH_2020-08-05

3410-T1-1120_DaddysChoise_EU DECLARATION OF CONFORMITY

3410-T1-1130_Rev00_DC T0001-UNIVERSAL Module B Certificate.pdf

3410-T1-1131_Rev00_DC T0001-UNIVERSAL Module C2 Certificate

3410-T1-1132_Rev00_DC T0001-TUV EN149 FFP2 Test Report

3410-T1-1133_Rev00_DC T0001-CE BSI EU Type examination certificate

3410-T1-1134_Rev00_DC T0001-CE BSI ModuleC2 certificate

3410-T1-1140_Rev01_T0001_OPP_2020-09-19

3410-T1-1141_Rev01_T0001_OPP_2020-09-19

3410-T1-1150_Rev01_T0001_Box_2020-09-19

3410-T1-1151_Rev01_T0001_Box_2020-09-19

3410-T1-1160_Rev01_T0001_Carton_2020-09-19

3410-T1-1161_Rev01_T0001_Carton_2020-09-19