

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.

00	YT	30.10.2020	AStoyke	AStoyke	12.11.2020	FI	Approved for Delivery
Rev.	Name	Date	Name	Name	Date	Status	Kind of Revision
	<b>Prepared/Changed</b>		<b>Checked</b>	<b>Released</b>			

Copying of this document, and disclosure of it to others and the use or communication of the contents thereof, are forbidden without express written authority by Turktec GmbH (www.turktec.eu). Offenders are liable to the payment of damages. All rights are reserved in the event of the grant of a patent or the registration of an utility model or design.

Remarks:  
The responsibility of the IOM documentation is the Yiwu-Hamburg GmbH.



**Purism**



**6 Stk.**  
**Protective Face Mask**

**FFP2 NR**



Model: Purism  
Regulation (EU) 2016/425  
EN 149:2001 A1:2009 FFP2 NR

Free Area for Client Logo and Data



**OIM for Filtering Mask,**  
**Daddy's Choice Purism™ FFP2 NR**  
**3410-T1-9970**  
**www.daddys-choise.de**  
sales@daddys-choise.de

<b>YHH GmbH</b>	Product	<b>Daddy's Choice Purism</b>
	Type	<b>FFP2 NR</b>
	Standard	149:2009:2001
	Component	3410-T1-9970 - DC Purism FFP2 NR - Mask
Eng.Serv.-No.	<b>PO 3410-T1-2020-12-28</b>	
Eng.Serv.-Title		

Original Size	<b>A 4</b>	<b>QM &amp; OIM (Operating Instruction Manual)</b>
Scale	<b>1:1</b>	
DCC	Basis document	
DG	<b>GEN</b>	<b>Product documentation for the Filtering Mask "DC Purism"</b> <b>General design for FFP2 Mask according EU Standard</b> <b>EN149:2001+A1:2009 FFP2 NR</b>

## Table of Contents

See page

<b>1</b>	<b>OPERATION &amp; MAINTENANCE MANUALS &amp; INSTRUCTIONS- PROCESS .....</b>	<b>3</b>
1.1	About this manual .....	3
1.1.1	<i>Purpose and scope</i> .....	4
1.1.2	<i>Presentation conventions</i> .....	4
1.1.3	<i>Safety and warning symbols</i> .....	4
1.2	Description of product.....	4
1.2.1	<i>General information</i> .....	4
1.2.2	<i>Design basis / Intended use</i> .....	5
1.2.3	<i>Main components</i> .....	6
1.2.4	<i>Technical data</i> .....	6
1.2.5	<i>Product modifications</i> .....	6
1.3	Safety .....	7
1.3.1	<i>Instructions</i> .....	7
1.3.2	<i>Essential safety principles</i> .....	7
1.3.3	<i>Limits of use</i> .....	7
1.3.4	<i>Storage</i> .....	8
1.3.5	<i>Lifetime</i> .....	8
1.4	Maintenance .....	8
1.5	Service and spare parts.....	8
1.6	Attachments.....	8
1.6.1	<i>Declaration of conformity (EC) Manufacturer</i> .....	8
1.6.2	<i>Safety data sheets (chemicals)</i> .....	8
1.6.3	<i>Local check list</i> .....	8
1.6.4	<i>Drawings</i> .....	8
<b>2</b>	<b>NORM AND REGULATION / ADDITIONAL ATTACHMENTS .....</b>	<b>8</b>
2.1	Norms, Regulations, Directives .....	8
2.1.1	<i>DIN, EN</i> .....	9
2.1.2	<i>Regulation</i> .....	9
2.1.3	<i>Directives</i> .....	9
2.1.4	<i>Auflagen Behörde / Genehmigungen / Vergleiche</i> .....	9
2.2	Declaration of Conformity .....	9
<b>3</b>	<b>MAIN VENDOR INFORMATION OF PRODUCT .....</b>	<b>10</b>
3.1	Vendor .....	10
3.1.1	<i>Vendor/Manufacturer Info</i> .....	10
3.1.2	<i>Company Registration</i> .....	10
3.1.3	<i>Packing List</i> .....	10
3.1.4	<i>Product Stamp and Number</i> .....	10
3.1.5	<i>Sub Supplier EU Declaration of Conformity</i> .....	11
3.1.6	<i>Sending Documents</i> .....	11
<b>4</b>	<b>ATTACHMENTS.....</b>	<b>11</b>

# 1 Operation & maintenance manuals & instructions- Process

## 1.1 About this manual

This [•] ("Manual") is proprietary to Yiwu Hamburg GmbH and its affiliated companies ("Yiwu-Hamburg GmbH"). This Manual is intended for the use of Yiwu-Hamburg GmbH's customers only for the purposes of the agreement under which the document is submitted and no ownership rights are hereby transferred. No part of the Manual shall be used, reproduced, translated, converted, adapted, stored in a retrieval system, communicated or transmitted by any means, for any commercial purpose, including without limitation, sale, resale, licence, rental or lease, without the prior express written consent of Yiwu-Hamburg GmbH.

Customer understands and accepts that the information in this Manual is subject to any change without notice. It is the customer's responsibility to determine whether there have been any such updates or amendments. The Manual has been prepared to be used by professional and properly trained personnel, and the customer assumes full responsibility when using it. Dispute the fact that every effort has been made to ensure that the information in this Manual is accurate Yiwu-Hamburg GmbH does not make any representations, warranties or guarantees, express or implied, as to the accuracy or completeness of the Manual. In case of any discrepancies between different language versions English version shall prevail. Yiwu-Hamburg GmbH shall not be liable in contract, tort or in any other manner whatsoever to any person for any loss, damage, injury, liability, cost or expense of any nature, including without limitation incidental, special, direct or consequential damages arising out of or in connection with the use of the Manual. Yiwu-Hamburg GmbH's liability for any errors in the Manual is limited to the documentary correction of errors.

Yiwu Hamburg GmbH logo is a registered trademark of Yiwu Hamburg GmbH.

Other product names mentioned in this Manual may be trademarks of their respective companies, and they are mentioned for identification purposes only.

Copyright © Yiwu Hamburg GmbH 2021. All rights reserved.

### Yiwu Hamburg GmbH

**Address:** Baumgartenstraße 14a

26122 Oldenburg , Germany

**Telephone:** +49 173 5276974

**Fax:** +49 -

**Internet:** [www.yiwu-hamburg.com](http://www.yiwu-hamburg.com)

**Mail:** [info@yiwu-hamburg.com](mailto:info@yiwu-hamburg.com)

Distribution | Internet: [www.daddys-choise.de](http://www.daddys-choise.de)

Distribution | Mail: [sales@daddys-choise.de](mailto:sales@daddys-choise.de)

**Commercial Registry:** Commerce HB / Germany | Reg-ID-Nr.: HRB 31835




### 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

 <b>DANGER</b>	<b>DANGER</b> indicates a hazard with a high level of risk which, if not avoided, will result in death or serious injury.
 <b>WARNING</b>	<b>WARNING</b> indicates a hazard with a medium level of risk which, if not avoided, could result in death or serious injury.
 <b>CAUTION</b>	<b>CAUTION</b> 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 DC Purism 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™ Purism
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 with Clip
Protection Level	FFP2 NR
Size	One Size Fits Most
Sterility	NonSterile
Style	Flat Fold
Type	Respirator
User	Adult
Quantity	1.300.000
Package	6 Pcs / Box
Carton	400 Boxes
Built	2020-12-28

## 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:

**SGS Fimko Oy (NB0598)**

SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland

Certification No.: FI20/966301

Test report for FFP2 Mask: SL22002253011901TX

**Benannte Stelle für QM (Product Service) nach EU Directive 2016/425 und 89/686/EEC**

Notified body for EU Type Quality Management certificate according EU Directive 2016/425 Module C2 and 89/686/EEC:

**SGS Fimko Oy (NB0598)**

SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland

Certification No.: CN20/42187

Test report for FFP2 Mask: NA

**Benannte Stelle für Produkt Verifikation nach EU Directive 2016/425 und 89/686/EEC**

Notified body for EU Type product verification according EU Directive 2016/425 Module C2 and 89/686/EEC:

**TÜV Rheinland (Notified Body number: 0123),**

Test Report verification of Purism via TÜV Rheinland, located in Shanghai, PR. China

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

Certification No.: 244267961a 001

## 1.2.5 Product modifications

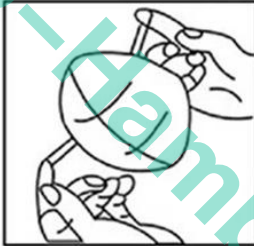
N/A

## 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:

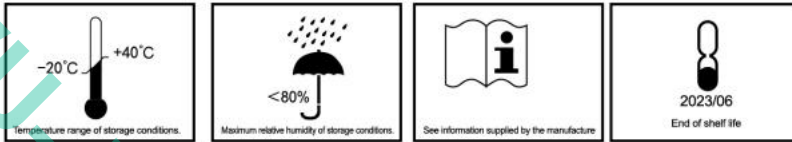
Do not use the respirator or enter or stay in a contaminated area under the following circumstances:

- 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) Manufacturer

See attachments

#### 1.6.2 Safety data sheets (chemicals)

See attachments

#### 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 Attachments

#### Box for the Masks

See Attachments

#### Transport Carton for the Boxes

See Attachments

## 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](http://www.3m.com)
- Covid19, Liste-der-Gueter (see attachment).

## 2.2 Declaration of Conformity

3410-T1-DC Purism MASK FFP2 CE\_YHH\_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-Purism-DC MASK FFP2 CE\_YHH\_2020-11-14

3410-T1-1020\_DaddysChoise\_EU DECLARATION OF CONFORMITY

3410-T1-1030\_Rev00\_Purism-DC\_SGS NB0598 Purism FFP2 NR Module B

3410-T1-1031\_Rev00\_Purism-DC\_Mask-CE-SGS-EN149-FFP2\_Test Report

3410-T1-1032\_Rev00\_Purism-DC\_SGS NB0598 Purism FFP2 NR Module C2证书

3410-T1-1033\_Rev00\_Purism-DC\_TÜV Rheinland - Purism 244267961a 001

3410-T1-1052\_Rev00\_Box\_2020-12-28\_Side A

3410-T1-1053\_Rev00\_Box\_2020-12-28\_Side B

3410-T1-1060\_Rev01\_Carton\_2020-09-19

3410-T1\_TT-Deed\_of\_Assignment\_2020-12-28-YHH

3410-T1\_Inspections and Tests to be Conducted\_Quality Plan / NA

3410-T1\_9970-1\_装箱单 Packing-List非医用