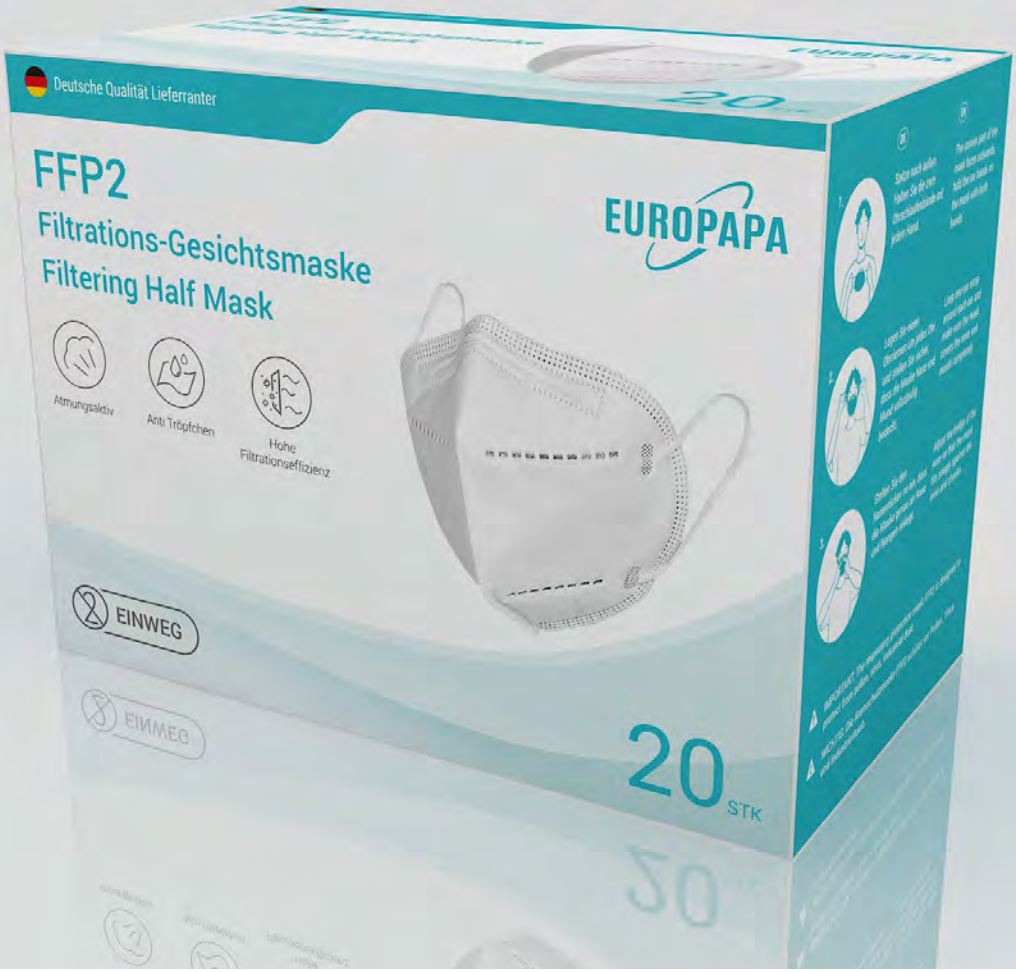

Deutsche Qualität Lieferranter
FFP2
Filtrations-Gesichtsmaske
Filtering Half Mask
EUROPAPA
Atmungsaktiv
Anti Tröpfchen
Hohe Filtrationseffizienz
EINWEG
20 STK

FFP2

Filtrations-Gesichtsmaske

Filtering Half Mask

EUROPAPA

EINWEG

20 STK

DE

1. Spitze nach außen. Halten Sie die zwei Ohrschlaufenbänder mit jedem Hand.

2. Legen Sie einen Ohrriemen um jedes Ohr und stellen Sie sicher, dass die Maske Nase und Mund vollständig bedeckt.

3. Stellen Sie den Nasenrücken so ein, dass die Maske genau an Nase und Wangen anliegt.

EN

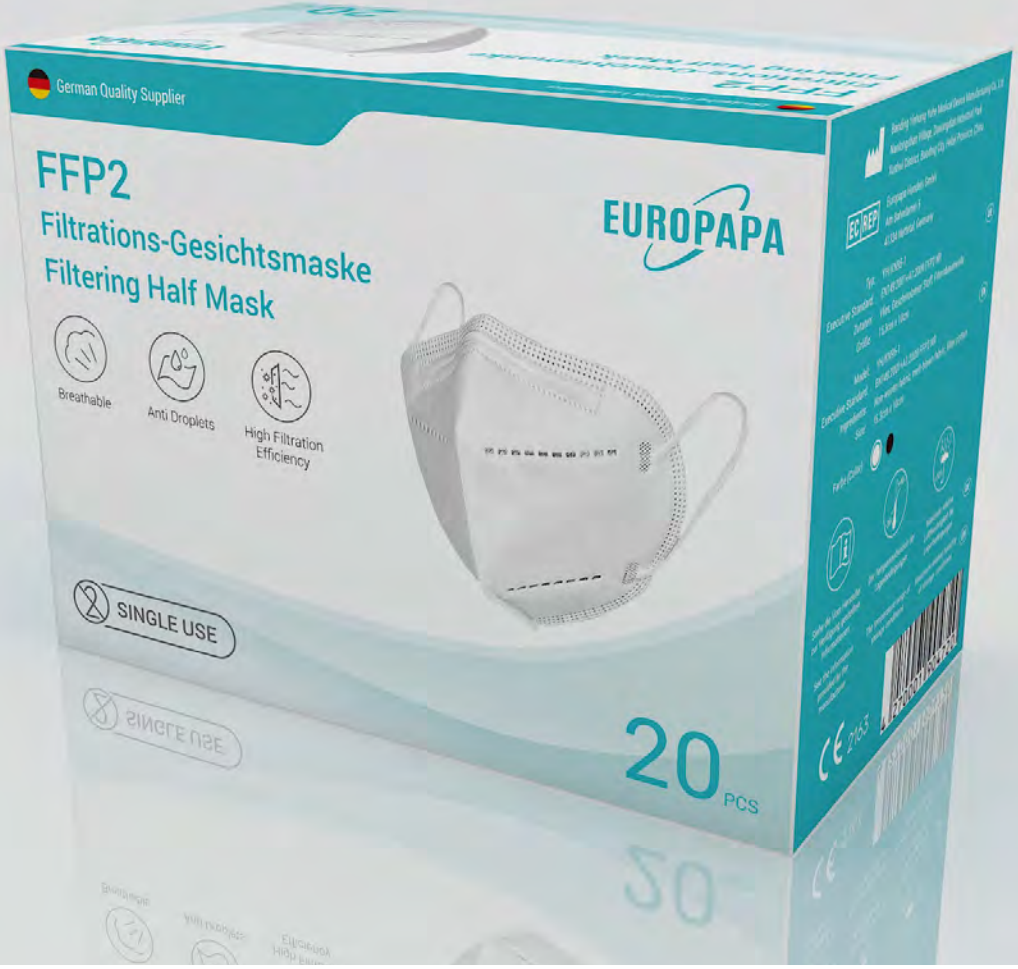
1. The convex part of the mask faces outwards, hold the ear bands on the mask with both hands.

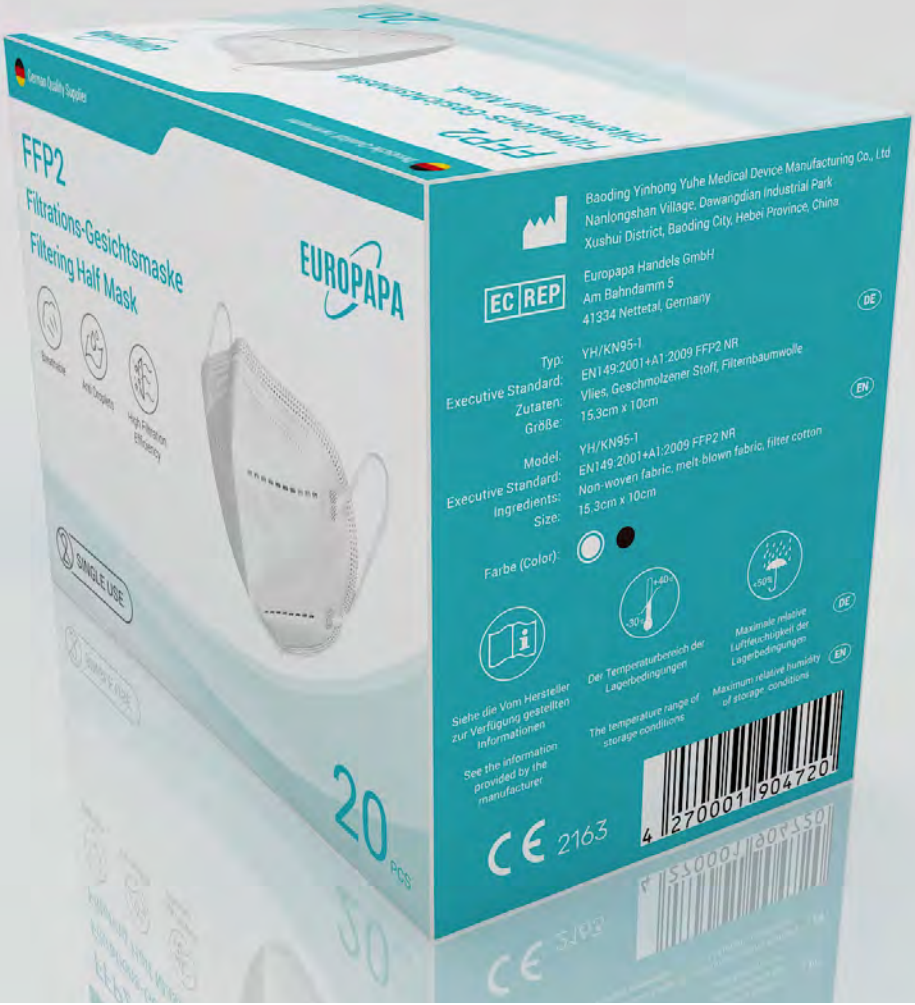
2. Loop one ear strap around each ear and make sure the mask covers the nose and mouth completely

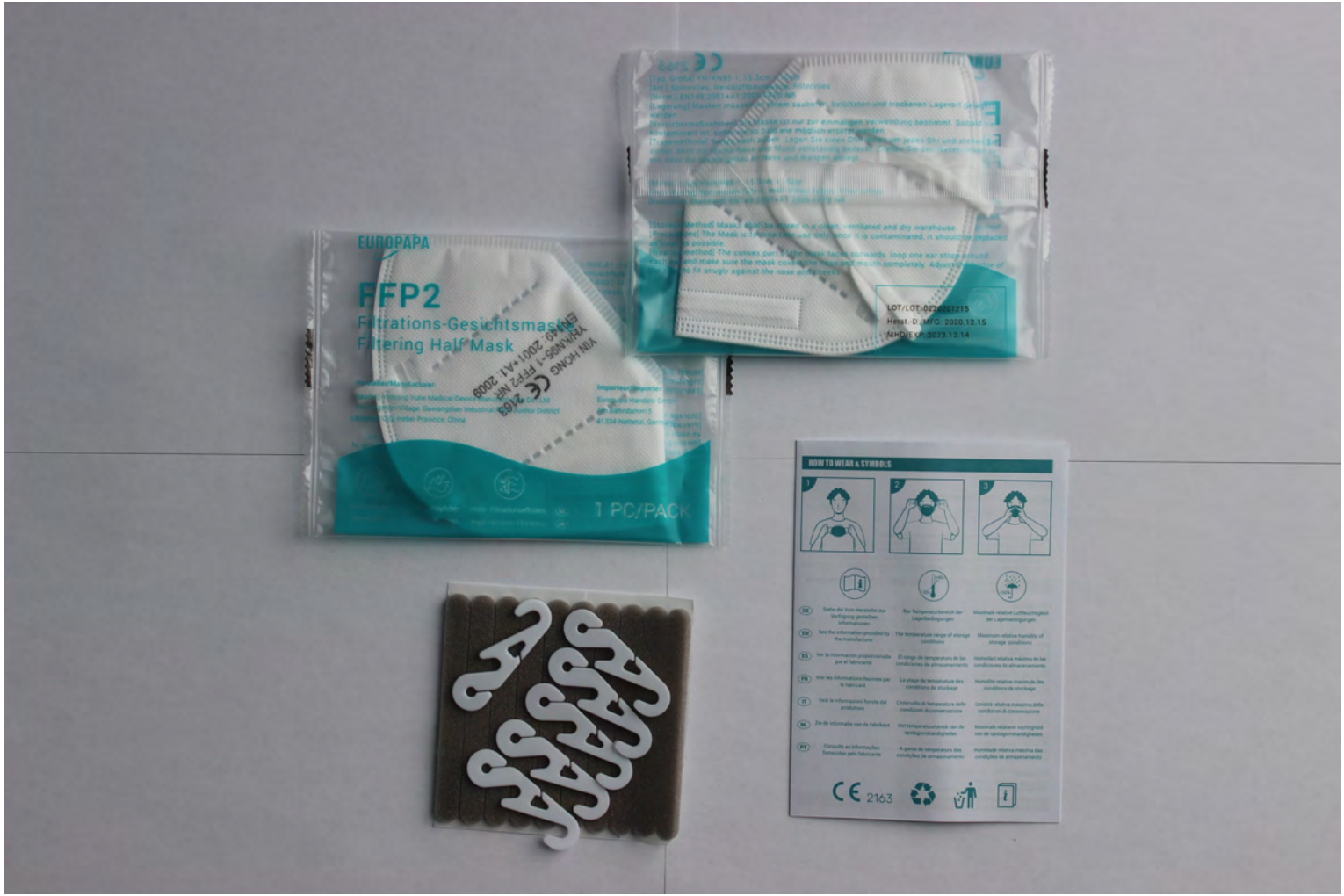
3. Adjust the bridge of the nose so that the mask fits snugly against the nose and cheeks.

IMPORTANT: The respiratory protection mask FFP2 is designed to protect from pollen, virus, industrial dust.

WICHTIG: Die Atemschutzmaske FFP2 schützt vor Pollen , Virus und Industriestaub.

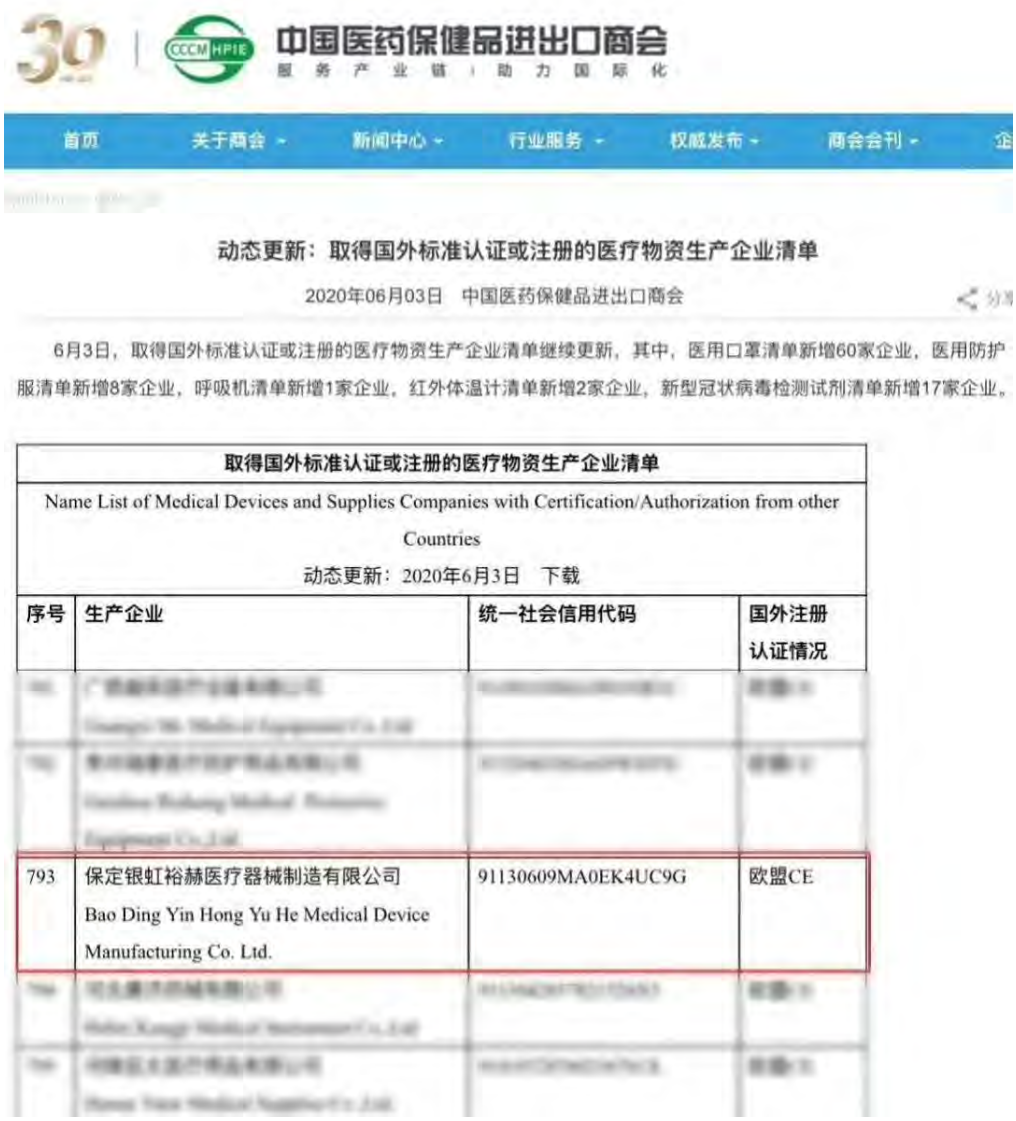

German Quality Supplier
FFP2
Filtrations-Gesichtsmaske
Filtering Half Mask
EUROPAPA
Breathable
Anti Droplets
High Filtration Efficiency
SINGLE USE
20 PCS
EC REP


German Quality Supplies
FFP2
Filtrations-Gesichtsmaske
Filtering Half Mask
EUROPAPA
SINGLE USE
20 PCS
Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd
Nanlongshan Village, Dawangdian Industrial Park
Xushui District, Baoding City, Hebei Province, China
EC REP
Europapa Handels GmbH
Am Bahndamm 5
41334 Nettetal, Germany
DE
Typ: YH/KN95-1
Executive Standard: EN149:2001+A1:2009 FFP2 NR
Zutaten: Vlies, Geschmolzener Stoff, Filternbaumwolle
Größe: 15,3cm x 10cm
EN
Model: YH/KN95-1
Executive Standard: EN149:2001+A1:2009 FFP2 NR
Ingredients: Non-woven fabric, melt-blown fabric, filter cotton
Size: 15.3cm x 10cm
Farbe (Color):
-30°
+40°
+50%
DE
Siehe die Vom Hersteller zur Verfügung gestellten Informationen
Der Temperaturbereich der Lagerbedingungen
Maximale relative Luftfeuchtigkeit der Lagerbedingungen
EN
See the information provided by the manufacturer
The temperature range of storage conditions
Maximum relative humidity of storage conditions
CE 2163
4 270001 904720


EUROPAPA
FFP2
Filtrations-Gesichtsmaske
Filtering Half Mask
1 PC/PACK
LOT/LOT:0220201215
Herst.-D./M.FG: 2020.12.15
MHD/EXP: 2023.12.14
HOW TO WEAR & SYMBOLS
CE 2163


48cm
FFP2
Filtrations-Gesichtsmaske
Filtering Half Mask
EUROPAPA
Manufacturer:
Baoding Yinhong Yuhe Medical Device Manufacturing Co.,Ltd
Nanlongshan Village Dawangdian Industrial Park, Xushui District
Baoding City, Hebei Province, China
Importer:
Europapa Handels GmbH
Am Bahndamm 5, 41334 Nettetal, Germany
1000 PCS/CTN
62.5cm
Filtering Half Mask
Specification:
Gross Weight: 9.6kg
Size: 62.5x34x48cm
LOT:
MFG: 2020.12.15
EXP: 2023.12.14
Made in China
34cm

In the Name List of Medical Devices and Supplies Companies



中国医药保健品进出口商会
服务产业链 助力国际化

首页 关于商会 新闻中心 行业服务 权威发布 商会会刊

动态更新：取得国外标准认证或注册的医疗物资生产企业清单

2020年06月03日 中国医药保健品进出口商会

6月3日，取得国外标准认证或注册的医疗物资生产企业清单继续更新，其中，医用口罩清单新增60家企业，医用防护服清单新增8家企业，呼吸机清单新增1家企业，红外体温计清单新增2家企业，新型冠状病毒检测试剂清单新增17家企业。

取得国外标准认证或注册的医疗物资生产企业清单			
Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries 动态更新：2020年6月3日 下载			
序号	生产企业	统一社会信用代码	国外注册认证情况
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
793	保定银虹裕赫医疗器械制造有限公司 Bao Ding Yin Hong Yu He Medical Device Manufacturing Co. Ltd.	91130609MA0EK4UC9G	欧盟CE
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

UNIVERSAL CERTIFICATION

UNIVERSAL CERTIFICATION AND SURVEILLANCE SERVICES TRADE CO.
Notified Body 2163

Date: 08.05.2020

Confirmation Letter,

Applicant Body	BAODING YINHONG YUHE MEDICAL DEVICE MANUFACTURING CO., LTD.
Address	Nanlongshan village, Dawangdian Industrial Park, Xushui District, Baoding City, Hebei Province, China
Contract No	CE-PPE-2305
Contract Date	08.05.2020

To whom it may concern,

This letter is to confirm that *Baoding Yinhong Yuhe medical device manufacturing Co., Ltd.* Company Address: *Nanlongshan village, Dawangdian Industrial Park, Xushui District, Baoding City, Hebei Province, China* has entered into the service agreement *CE-PPE-2305* with UNIVERSAL CERTIFICATION with regards to the application of Module B EU Type Examination Certification and Module C2 production monitoring for Particle filtering half masks, Model: *YH/KN95-1* within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III.

In case of any doubt about the integrity of this letter, please contact UNIVERSAL CERTIFICATION by email (info@universalcert.com) to verify.

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. LTD. ŞTİ.

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

The validity of this letter can be verified online.

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-706

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd.
Nanlongshan village, Dawangdian Industrial Park, Xushui District, Baoding City, Hebei Province, China

are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: YINHONG **Model:** YH/KN95-1
Filtering half mask
Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **04/06/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-706/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd.

Nanlongshan village, Dawangdian Industrial Park, Xushui District, Baoding City, Hebei Province, China

Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
YINHONG / YH/KN95-1	FFP2 NR	2163-PPE-706	04.06.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **21/06/2020** and will be valid for one year, until **20/06/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

UNIVERSAL
CERTIFICATION

TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 04.06.2020 / 2163-KKD-706

Client: Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd.

Address: Nanlongshan village, Dawangdian Industrial Park, Xushui District, Baoding City, Hebei Province, China

This report is for the, given above, manufacturer, prepared according to the test results obtained from Jiangsu Guojian Testing Technology Co. Ltd. accredited by CNAS (Chinese Accreditation Body), signatory to ILAC MRA, with number CNAS L10118 for the product identified below, dated 12.05.2020 with Serial Id 2020-WSZ FHL 4412 based on EN 149: 2001 + A1: 2009 standard.

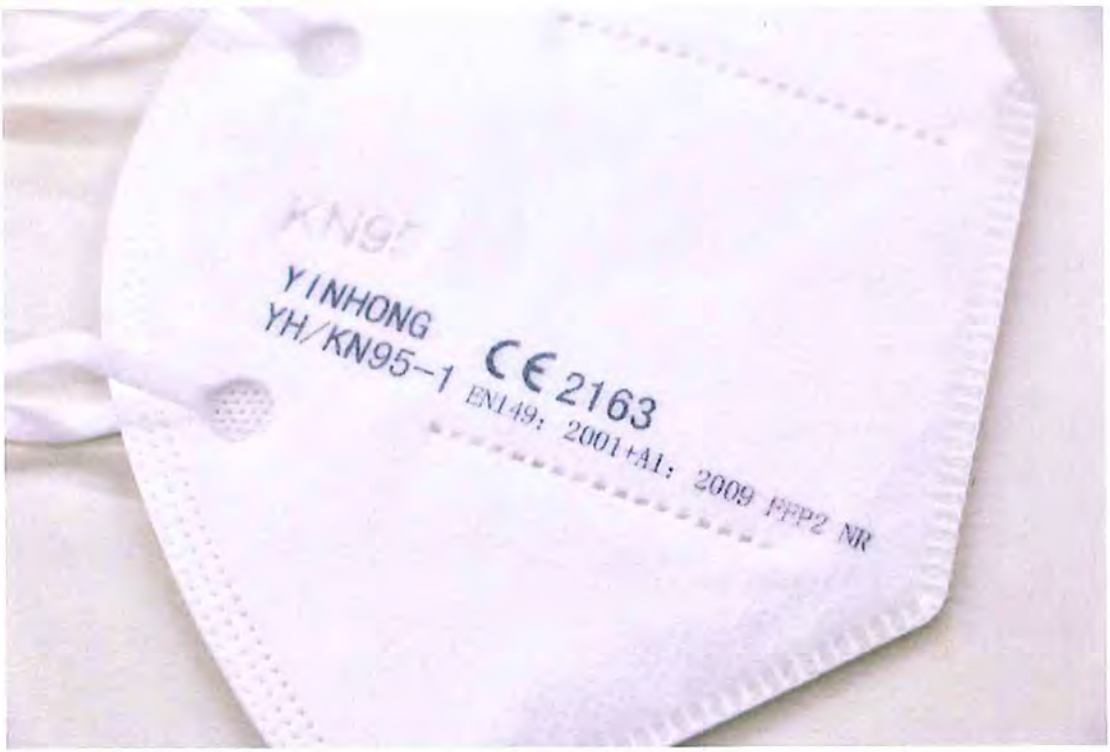
The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

Product Description: Particle Filtering Half Mask

Classification: FFP2 NR

Brand Name: YINHONG **Model:** YH/KN95-1



UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

THE CLAUSES OF EN 149: 2001 + A1: 2009 STANDARD RELATED TO EUROPEAN UNION DIRECTIVE EU 2016/425 REQUIREMENTS

1.1. Design principles

1.1.1. Ergonomics

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest prossible level.

1.1.2. Levels and classes of protection

1.1.2.1. Highest level of protection possible

The optimum level of protection to be taken into account in the design is that beyond which the constraints by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

1.2. Innocuousness of PPE

1.2.1. Absence of risks and other inherent nuisance factors

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under fore seeable conditions of use.

1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries

1.2.1.3. Maximum permessible user impediment

Any inpediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

1.3 Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

1.3.2. Lightness and design strength

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use

1.4. Information supplied by the manufacturer

The notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

a) In addition to the name and addressof the manufacturer and/or his authorized representative established in the Community
b) Storage, use, cleaning, maintenance, servicing and disinfection. cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in guestion;
d) Suitable PPE accessories and the characteristics of appropriate spare parts;
e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
f) The obsolescence deadlineor period of obsolescence of PPEor certain of its components;
g) The type of packaging suitable for transport;
h) The significance of any markings(see 2.12)
i) Where appropriate the references of the Directives applied inaccordance with Article5(6) (b);
j) The name, address and identification number of the notified body involved in the design stage of the PPE

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination

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2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.
The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.
If necessary, such PPE must be treated or provided with means to prevent misting-up.
Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.
If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.
Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

2.6. PPE for use in potentially explosive atmospheres

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

2.8. PPE for intervention in very dangerous situations

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.
The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.
Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

2.9. PPE incorporating components which can be adjusted or removed by the user

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must rem ain perfectly legible throughout the foreseeableuseful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.
If PPE (or a PPE component) is too small to allow al lor part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.10.2. Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.
To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.
Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

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CERTIFICATION

Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the (EU) 2016/425 Directive

Conforming to EN 149:2001 + A1:2009 Standard Requirements

Article 5

Classification: Particle Filtering Half Mask
Total Inward Leakage: Classification – FFP2

Article 7.4

Packing: Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage.

Article 7.5

Material: Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning reports; It is understood withstand handling and wear over the period for which the particle filtering half mask is designed to be used suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer.

Article 7.6

Cleaning and Disinfection: Particle filtering half mask is **not** designed to be as re-usable.

Article 7.7

Practical Performance :

Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result
1.The face piece fitting	2	0	Positive results are obtained from the performance tests related to the implementation under real conditions, applied with the compatibility with skin evaluation (7.10). **No imperfections**
2.Head harness comfort	2	0	
3.Security of fastenings	2	0	
4.Speech clearness	2	0	
5.Field of vision	2	0	
6.Materials compatibility with skin	10	0	

Conditioning : (A.R.) As Received, original

Article 7.8

Finish of Parts: Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.

Article 7.9.1

Total Inward Leakage:

The Total Inward Lekage test is conducted by 10 individual in a aerosol chamber with a walking band, and samples are taken during the condcution of the excercises defined in the standard. The samples used in the test are subjected to the conditioning required in the standard as Temperature conditioning and as received.

It was reported that;
All 50 exercise measurement results are smaller or equal to 11%, According to the results maximum measurement is 7,8 %.
All 10 individual's arithmetic mean is smaller or equal to 8%, According to the results the means for 10 subject varies between 6,3 % to 7,8 %.

According to the reported results, the product meets the limits for FFP1 and FFP2 classification.

Article 7.9.2

Penetration of filter material: Sodium Chloride Testing

Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	0,2	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first, and second protection classes. **FFP1, FFP2**
(A.R.)	-	0,3		
(A.R.)	-	0,2		
(S.W.)	-	0,1		
(S.W.)	-	0,2		
(S.W.)	-	0,2		
(M.S. T.C.)	-	0,6		
(M.S. T.C.)	-	0,5		
(M.S. T.C.)	-	0,6		

Conditioning : (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

95 L/min = 1,6 $dm^3.sn^{-1}$

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Article 7.9.2

Penetration of filter material: : Paraffin Oil Testing

Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	3,1	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first and second protection classes. **FFP1, FFP2**
(A.R.)	-	3,0		
(A.R.)	-	2,8		
(S.W.)	-	2,8	FFP2 ≤ 6 %	
(S.W.)	-	3,0		
(S.W.)	-	3,0		
(M.S. T.C.)	-	5,8	FFP3 ≤ 1 %	
(M.S. T.C.)	-	5,9		
(M.S. T.C.)	-	5,8		

Conditioning : (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

Article 7.10

Compatibility with skin: In Practical Performance report, the likelihood of mask materials in contact with the skin causing irritation or other adverse effect on health was not reported.

Article 7.11

Flammability :

Condition	No. of Sample	Visual inspection	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	0,1s	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	**Passed** Filtering half masks fulfill requirements of the standard
(A.R.)	-	0,1s		
(T.C.)	-	0,1s		
(T.C.)	-	0,1s		

Conditioning : (A.R.) As Received, original
(T.C.) Temperature Conditioning

Article 7.12

Carbon dioxide content of the inhalation air:

Condition	No. of Sample	CO_2 content of the inhalation air [%] by volume	An average CO_2 content of the inhalation air	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	0,08	0,08	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	**Passed** Filtering half masks fulfill requirements of the standard
(A.R.)	-	-			
(A.R.)	-	-			

Conditioning : (A.R.) As Received, original

Article 7.13

Head harness: In Practical Performance report, No adverse effects have been reported for holding the mask of the head harness firmly in position, for total inward leakage properties. Tested on samples number 9 to 18.

Article 7.14

Field of vision: In Practical Performance report, no adverse effects were reported for the field of vision features.

Article 7.16

Breathing Resistance: Inhalation

The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temparature conditioning and 3 Ssimulated wearing conditioned, complies with the limits given in the standard for FFP1, FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min.

Passed.

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

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Article 7.17.2	**Clogging:** This test is not applied to Particle Filtering Half Mask which is not reusable. *(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)*
Article 7.17.3	**Penetration of filter material:** This test is not applied to Particle Filtering Half Mask which is not reusable.
Article 7.18	**Demountable Parts:** There are no demountable parts on the product.
Article 9	**Marking – Packaging:** Necessary markings are available on the product and its packaging.
Article 10	**Information to be supplied by the manufacturer:** In each of the smallest commercially available packaging of the product, implementation (installation instruction) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined.

PREPARED BY	APPROVED BY
Osman CAMCI PPE Expert	**Suat KAÇMAZ** Director

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

Erklärung / DECLARATION

Produkt / Product: Filtering Half Mask

Typ / Model: YH/KN95-1

Einstufung / Classification: FFP2 NR

Sehr geehrte/er Kundin/Kunde,

Hiermit erklären wir, dass unser Unternehmen kürzlich nach dem neuen deutschen Gesetz die Verpackung unserer Produkte verbessert und aktualisiert hat. Die neuen Verpackungsprodukte unterscheiden sich nur von den alten Verpackungsprodukten in der Außenverpackung, die Qualität der Produkte ist gleichbleibend. Die Produkte in beiden Paketen erfüllen alle die EU-Exekutivnormen EN149: 2001 + A1: 2009 und beide sind die gleichen wie die Produkte des Dekra-Testberichts.

Dear Customer,

We Hereby declare that our company has recently improved and upgraded the packaging of our products according to the latest regulations of Germany. The new packaging products are only different from the old packaging products in the outer packing, the quality of the products is consistent. The products in both packages are all meet EU executive standards EN149:2001+A1:2009, and both are the same as the products of Dekra test report.

Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd

Quality Management Representative

November 01, 2020

Bewertung der Konformität von Corona SARS-Cov-2 Pandemie Atemschutz (CPA) nach dem Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken Revision 1
Evaluation of the conformity of corona sars-cov-2 pandemic respiratory protection (CPA) according to the testing principle for corona sars-cov-2 pandemic respiratory protection masks revision 1

Berichtsnummer *Report number*	3418059.10-CPA
Prüfgegenstand *Test subject*	Corona SARS-CoV-2 Atemschutzmaske *Corona SARS-CoV-2 respiratory protective mask*
Modell *Type*	YH/KN95-1
Hersteller *Manufacturer*	Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd. Nanlongshan Village, Dawangdian Industrial Park, Xushui District, Baoding City, CHINA
Importeur *Importer*	Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd. Nanlongshan Village, Dawangdian Industrial Park, Xushui District, Baoding City, CHINA

Die Anforderungen des Prüfgrundsatzes sind *The requirements of the test principle are*	✓ Erfüllt *Fulfilled*

Die technische Wirksamkeit des oben genannten Produkts ist im Rahmen der Empfehlung (EU) 2020/403 der Europäischen Kommission vom 13. März 2020 über Konformitätsbewertungs- und Marktüberwachungsverfahren im Kontext der COVID-19 Bedrohung zu vermuten.
The technical efficiency of the above-mentioned product is to be presumed within the framework of the European Commission Recommendation (EU) 2020/403 of 13th March 2020 on conformity assessments and market surveillance procedures in the context of the COVID-19 risk.

Der Prüfgrundsatz kann unter der Website der ZLS eingesehen werden.
The test principle can be accessed under the ZLS website.

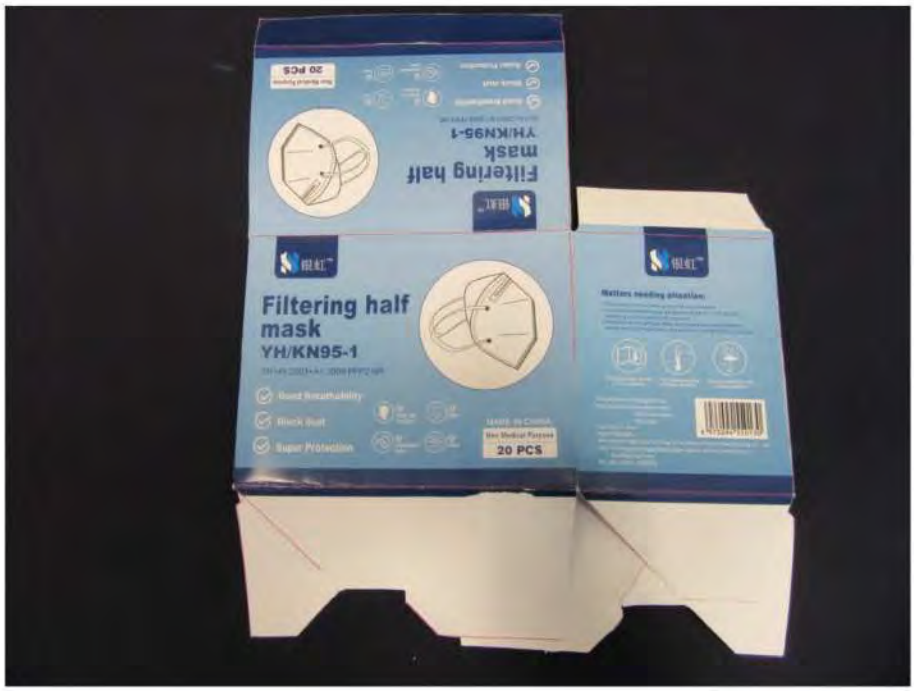
Diese Bewertung ist gültig vom 19.06.2020 bis 19.06.2021.
This evaluation of conformity is valid from 2020-06-19 until 2021-06-19.

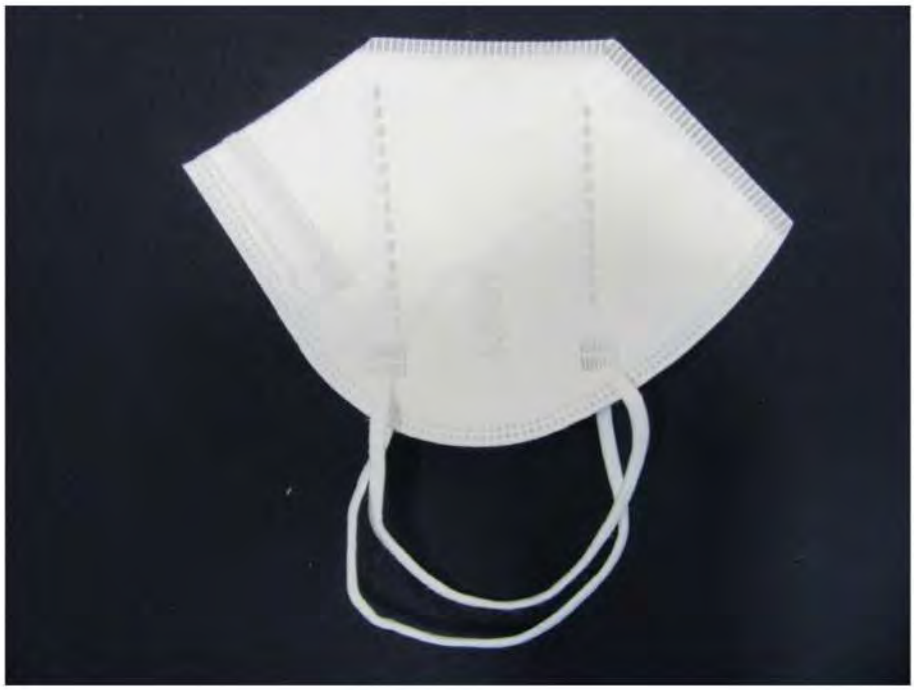
DEKRA Testing and Certification GmbH
Bochum, 2020-06-19

Jörg-Timm Kilisch
Geschäftsführer *Managing Director*

DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart
Zertifizierungsstelle: Dinnendahlstraße 9, 44809 Bochum,
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.com

YH/KN95-1





DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart
Zertifizierungsstelle: Dinnendahlstraße 9, 44809 Bochum,
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.com

DEKRA Testing and Certification GmbH
Standort Essen
Persönliche Schutzausrüstungen

Adlerstraße 29
45307 Essen, Germany

Tel +49.201.52319-0
Fax +49.201.52319-401
E-Mail CPA@dekra.com

Prüfbericht / *Test report*
No. 3418059.10-CPA

Prüfgegenstand *Testsubject*	Corona SARS-CoV-2 Atemschutzmaske *Corona SARS-CoV-2 respiratory protective mask*
Modell *Type*	YH/KN95-1
Hersteller *Manufacturer*	Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd. Nanlongshan Village, Dawangdian Industrial Park, Xushui District, Baoding City, CHINA
Prüfgrundlage *Test requirement*	Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken Rev. 1 vom 26.03.2020 *Testing principle for Corona SARS-CoV-2 pandemic respiratory masks rev. 1 of 2020-03-26*
Prüfergebnis *Test result*	Die Pandemie Atemschutzmaske entspricht der Corona SARS-CoV-2 Prüfanforderungen *The pandemic respiratory protective mask does meet the Corona SARS-CoV-2 test requirements.*
Datum *Date of issue*	19.06.2020

Dieser Bericht besteht aus 14 Seiten. *This report consists of 14 pages.*

DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart
Zertifizierungsstelle *Certification Body*: Dinnendahlstraße 9, 44809 Bochum
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.com

Veranlassung / *Reason*

Auftragseingang *Date of order*	11/05/2020
Auftraggeber *Applicant*	Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd. Nanlongshan Village, Dawangdian Industrial Park, Xushui District, Baoding City, CHINA
Importeur *Importer*	Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd. Nanlongshan Village, Dawangdian Industrial Park, Xushui District, Baoding City, CHINA
Eingang der Prüfmuster *Date of receipt of test item*	27/05/2020
Prüfzeitraum *Date (s) of performance of tests*	27/05/2020 – 10/06/2020
Prüfstandort *Test location*	DEKRA Testing and Certification GmbH Persönliche Schutzausrüstungen Adlerstraße 29, 45307 Essen, Germany

Zusammenfassung der Prüfung / *Summary of Testing*

Prüfung *Test*		**bestanden** *pass*	**nicht bestanden** *fail*	**nicht anwendbar** *not applicable*
2.2	Sichtprüfung / *Visual inspection*	✓		
2.3	Anlegeprüfung / *Donning test*	✓		
2.4	Durchlass des Filtermediums / *Penetration of the filter medium*	✓		
2.5	Ausatemventil(e) / *Exhalation valve(s)*	✓		
2.6	Atemwiderstand / *Breathing resistance*			
2.6.1	CPA ohne Ventil / *CPA without valve*	✓		
2.6.2	CPA mit Ventil / *CPA with valve*			✓
2.7	Kennzeichnung und Informationen des Herstellers / *Marking and manufacturer's information*	✓		

N/T Nicht getestet oder geprüft / *Not tested or checked*

Bemerkung / *Remarks*:

Die Prüfung gilt als „bestanden", wenn der ermittelte Messwert kleiner oder gleich dem vorgegebenen Grenzwert ist. Mögliche Erklärungen zu „nicht bestandenen" oder nicht durchgeführten Prüfungen können dem Glossar am Ende dieses Prüfberichts entnommen werden.

The test is considered as a "pass" if the measured value is less or equal to the limit.

Possible explanations for "failed" or not performed tests can be found in the glossary at the end of this test report.

DEKRA Testing and Certification GmbH

(Stockmann)

Prüfingenieur/ *Test engineer*

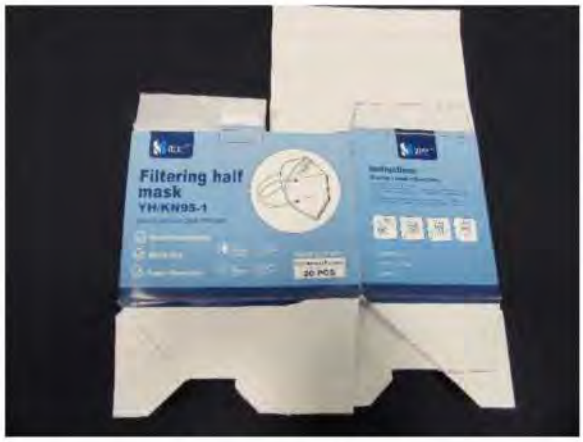
Inhaltsverzeichnis / *Table of contents*

1 Bezug der Prüfergebnisse / *Reference of the test results*

Die in diesem Bericht aufgeführten Ergebnisse beziehen sich ausschließlich auf die untersuchten Prüfmuster.
The results listed in this report refer only to the tested samples.
Für die Prüfung wurden folgende Dokumente zugrunde gelegt:
The following documents were taken as a basis for the tests:

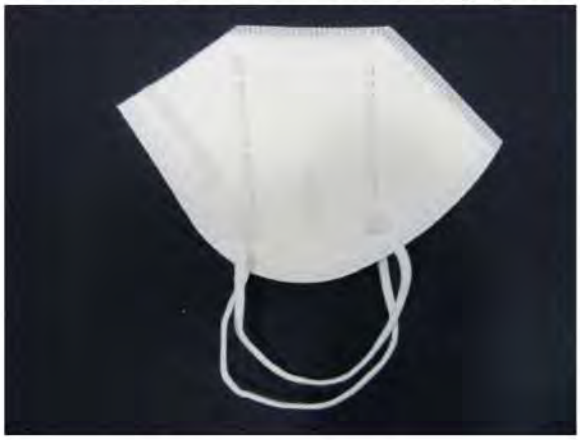
1	Verpackung / *packaging*

Die folgende Maske wurde geprüft / *The following mask was tested:*

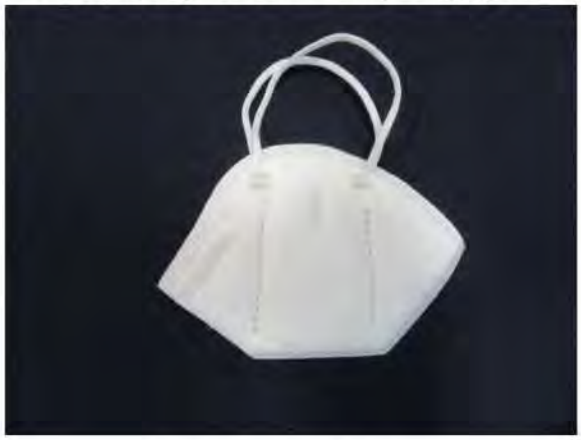


Umverpackung Vorderseite / *Outer packaging front*

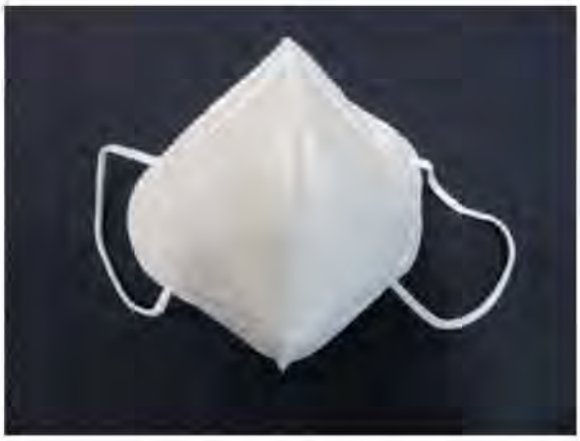
Umverpackung Rückseite/ *Outer packaging back*



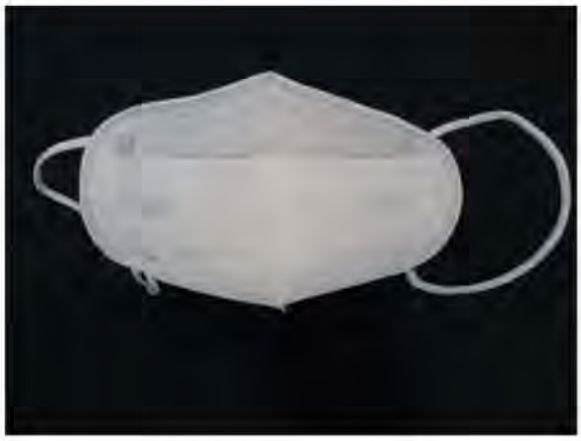
Seitenansicht / *Side view*



Seitenansicht / *Side view*



Frontalansicht / *Frontal view*



Innenansicht / *Inner view*

2 Prüfergebnisse / *Test results*

A Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken / *Testing principle for Corona SARS-CoV-2 pandemic respiratory masks*

Die nachfolgenden Ziffern entsprechen den Abschnitten des Prüfgrundsatzes für Corona SARS-Cov-2 Pandemie Atemschutzmasken.

The following numbers correspond to the paragraphs of the testing principle for Corona SARS-CoV-2 pandemic respiratory masks.

2 Anforderungen und Prüfungen / *Requirements and tests*

2.1 Übersicht der Prüfungen / *Overview of tests*

Prüfung *Test*	**Abschnitt EN 149:2001+A1:2009** *Section EN 149:2001+A1:2009*
Sichtprüfung *Visual inspection*	--
Anlegeprüfung *Donning test*	8.4.1
Durchlass des Filtermediums *Flow rate through the filter medium*	8.11
Ausatemventil-Durchströmung *Exhalation valve flow*	8.3.4
Atemwiderstand (Geräte ohne Ventil) *Breathing resistance (valveless devices)*	8.9.2 + 8.9.3
Atemwiderstand (Geräte mit Ventil) *Breathing resistance (valved devices)*	8.9.2 + 8.9.3
Konditionierung *Conditioning*	**Abschnitt EN 149:2001+A1:2009** *Section EN 149:2001+A1:2009*
Temperaturkonditionierung *Temperature conditioning*	8.3.2 nur *only* a)
Gebrauchssimulation *Simulation of wearing*	8.3.1

2.2 **Sichtprüfung** / *Visual inspection*

CPA müssen zum Verkauf so verpackt angeboten werden, dass sie gegen mechanische Beschädigung und Verunreinigung vor dem Gebrauch geschützt sind.
When supplied for purchase, the CPA must be packed in such a way that they are protected against mechanical damage and contamination prior to their use.

Ergebnis: *test result:*	Die Verpackung schützt die Maske vor mechanischer Beschädigung und Verunreinigungen. *The package protects the mask from mechanical damage and contamination.*	**bestanden** *pass*	**nicht bestanden** *fail*
		✓	

2.3 **Anlegeprüfung** / *Donning test*

Die CPA muss leicht an- und abgelegt werden können. Die Kopfbänderung muss kräftig genug sein, um die CPA in Position zu halten. Die CPA muss einen Dichtsitz am Gesicht der Testperson gewährleisten. Bei einem Trageversuch dürfen keine offensichtlichen Undichtigkeiten im Bereich der Dichtlinie der Maske erkennbar sein. Bei der Beatmung durch eine Testperson dürfen keine Luftströmungen, die durch Undichtigkeiten in der Dichtlinie (schlechte Anpassung an das Gesicht) entstehen, wahrnehmbar sein.
Putting on and removing the CPA must be done easily. The head straps must be strong enough to keep the CPA in place. The CPA must ensure a close fit at the face of the test person. When carrying the mask in a test, no obvious leakage along the sealing line of the mask shall be recognisable. When the test person uses the mask for breathing, no air flow shall be noticeable which is caused by leakage in the sealing line (poor facial fit).

Ergebnis: *test result:*	Die Kopfbänderung besteht aus dünnen flexiblen Bändern und die CPA konnte leicht angelegt und abgenommen werden. *The headgear consists of thin flexible straps and the CPA was easy to put on and take off.*	**bestanden** *pass*	**nicht bestanden** *fail*
		✓	

Ergebnis: *test result:*	Die Kopfbänderung ist kräftig genug, um die CPA in Position zu halten. *The headgear is strong enough to hold the CPA in place.*	**bestanden** *pass*	**nicht bestanden** *fail*
		✓	

Ergebnis: *test result:*	Bei einem Trageversuch waren keine offensichtlichen Undichtigkeiten im Bereich der Dichtlinie der CPA erkennbar oder bei einer Beatmung in Form von Luftströmungen wahrnehmbar. *During a wearing test, no obvious leaks were detected in the area of the sealing line of the CPA or were perceptible in the form of air currents during ventilation.*	**bestanden** *pass*	**nicht bestanden** *fail*
		✓	

2.4 Durchlass des Filtermediums / *Penetration of the filter medium*

Der Durchlass des Filters der CPA wird mit Paraffinöl mit 95 l/min geprüft. Es müssen insgesamt drei Muster der CPA geprüft werden. Die drei Muster werden wie folgt konditioniert: Temperaturkonditionierung nur bei hoher Temperatur und Gebrauchssimulation mit feuchter Beatmung für 20 Minuten. Die Prüfung erfolgt nach EN 149:2001+A1:2009 Abschnitt 8.11 mit der Prüfung des Durchlasses nach EN 13274-7:2008 Abschnitt 5.1 und 5.2. Der Durchlass der CPA aller drei Muster muss ≤ 6,0 % sein.

The penetration through the filter of the CPA is tested using paraffin oil at 95 l/min. In total, three samples of the CPA have to be tested. The three samples will be conditioned as follows: temperature conditioning only at high temperature, and simulation of wearing with moist respiration for 20 minutes. The test is carried out in accordance with section 8.11 of EN 149:2001+A1:2009 with the filter penetration according to EN 13274-7:2008 clause 5.1 and 5.2. The penetration of the CPA of all three samples must be ≤ 6.0 %.

Tabelle I Ergebnisse beim Kurztest (3 min) / *Table I Results during short test (3 min)*

Probe *Sample*[1]	**Konditionierung** *Conditioning*	**Durchlassgrad bei 95 l/min Paraffinöl** *Penetration at 95 l/min Paraffine oil* **[%]**	
		Anforderung *Requirement*	**Ergebnis** *Test result*
01	T.C. + S.W.	≤ 6,0 %	1,74
02	T.C. + S.W.		1,98
03	T.C. + S.W.		1,18

[1] Vom Prüflabor verwendete Bezeichnung. *Designation used by the testing laboratory.*
T.C.: Temperatur konditioniert / *Temperature conditioned*
S.W.: Gebrauchssimulation / *Usage simulation*

2.5 **Ausatemventil(e)** / *Exhalation valve(s)*

Die CPA darf ein oder mehrere Ausatemventil(e) haben. Sie müssen in jeder Lage richtig funktionieren. Die Prüfung muss nach EN 149:2001+A1:2009 Abschnitt 8.9.1 erfolgen. Falls ein Ausatemventil(e) vorhanden ist, muss es (müssen sie) nach einem 30 s dauernden kontinuierlichen Ausatemstrom von 300 l/min weiter richtig funktionieren. Die Prüfung erfolgt während der Messung des Atemwiderstandes. Wenn das Gehäuse des Ausatemventils am Maskenkörper befestigt ist wird mit einer gefühlten Kraft von 10 N per Hand an dem Ausatemventil bzw. an dessen Gehäuse gezogen. Löst sich das Ventil, gilt die Prüfung als nicht bestanden.
The CPA may have one or more exhalation valves; these must work properly in any position. The test has to be carried out in accordance with section 8.9.1 of EN 149:2001+A1:2009. If one or more exhalation valves are in place, they must continue to work properly after a continuous exhalation flow of 300 l/min for 30 s. The test is carried out during the measurement of the breathing resistance. Once the casing of the exhalation valve has been fastened to the mask body, the exhalation valve or its casing is manually pulled with a felt force of 10 N. If the valve comes loose, the test is deemed as not passed.

Ergebnis: *test result:*	Die CPA beinhaltet kein(e) Ausatemventil(e). *The CPA does not include (an) exhalation valve(s).*	**bestanden** *pass*	**nicht bestanden** *fail*
		✓	

2.6 Atemwiderstand / *Breathing resistance*

Die Atemwiderstände gelten für CPA mit und ohne Ventil(e).
The breathing resistance requirements apply to valved and valveless CPA.

2.6.1 CPA ohne Ventil / *CPA without valve*

Geprüft werden zwei CPA nach der Temperaturkonditionierung und der Gebrauchssimulation mit feuchter Beatmung für 20 Minuten. Die Prüfung erfolgt in Anlehnung an EN 149:2001+A1:2009 Abschnitt 8.9. Der Ausatemwiderstand wird in der Lage geradeaus sehend geprüft.
Der Atemwiderstand bei der Einatmung bei 95 l/min muss bei allen Mustern ≤ 3,0 mbar sein.
Der Atemwiderstand bei der Ausatmung bei 160 l/min muss bei allen Mustern ≤ 3,0 mbar sein.
2 CPA are tested after the temperature conditioning and the simulation of wearing with moist respiration for 20 minutes. The test is carried out following section 8.9 of EN 149:2001+A1:2009. The exhalation resistance is tested in the position "looking straight ahead".
The breathing resistance for inhalation at 95 l/min must be ≤ 3.0 mbar at all samples.
The breathing resistance for exhalation at 160 l/min must be ≤ 3.0 mbar at all samples.

Tabelle II Ergebnisse der Einatemwiderstandsmessungen bei 95 l/min
Table II Results of inhalation resistance measurements at 95 l/min

Probe *Sample*[1]	**Konditionierung** *Conditioning*	**Einatemwiderstand** *Inhalation resistance* **[mbar]**	
		Anforderung *Requirement*	**Ergebnis** *Test result*
04	T.C. + S.W.	≤ 3,0 mbar	1,19
05	T.C. + S.W.		1,28

[1] Vom Prüflabor verwendete Bezeichnung / *Designation used by the testing laboratory.*
T.C.: Temperaturkonditioniert / *Temperature conditioned*
S.W.: Gebrauchssimulation / *Usage simulation*

Tabelle III Ergebnisse der Ausatemwiderstandsmessungen bei 160 l/min
Table III Results of exhalation resistance measurements at 160 l/min

Probe *Sample*[1]	**Konditionierung** *Conditioning*	**Ausatemwiderstand** *Exhalation resistance* **[mbar]**	
		Anforderung *Requirement*	**Ergebnis** *Test result*
04	T.C. + S.W.	≤ 3,0 mbar	1,93
05	T.C. + S.W.		2,13

[1] Vom Prüflabor verwendete Bezeichnung. / *Designation used by the testing laboratory.*
T.C.: Temperaturkonditioniert / *Temperature conditioned*
S.W.: Gebrauchssimulation / *Usage simulation*

Gemessen in der ersten definierten Lage des Prüfkopfes / *Measured in the first defined position of the test head:*
geradeaussehend / *facing directly ahead*

2.7 Kennzeichnung und Informationen des Herstellers / *Marking and manufacturer's information*

Die Kennzeichnung der CPA oder der kleinsten Verpackungseinheit soll dokumentiert werden, sodass eindeutig erkennbar ist, welche CPA vorliegt.

The marking of the CPA or the smallest packing unit must be documented so that it becomes unmistakeably clear which CPA is provided.

Ergebnisse / *Test Results*		
	bestanden *pass*	**nicht bestanden** *fail*
Die CPA oder die kleinste Verpackungseinheit muss mit den folgenden Informationen gekennzeichnet sein: *The marking of the CPA or the smallest packing unit must contain the following information:*		
a) Name, Warenzeichen und/oder andere Angaben zur Identifikation des Herstellers; *a) Name, trademark and/or other details identifying the manufacturer;*	✓	
b) Typidentische Kennzeichnung (Nummer, Modell oder Ähnliches) *b) Marking identifying the type (number, model or similar)*	✓	
Informationen müssen jeder CPA oder der kleinsten Verpackungseinheit beigelegt sein. Die Informationen können in Textform oder beispielsweise in Piktogrammen dargestellt werden. Die Informationen müssen mindestens Angaben enthalten zu: *Information must be supplied with each CPA or smallest packing unit. This information can be displayed either as text or as pictograms, for example. The information must also provide at least details on:*		
a) Sitz sowie richtiges An- und Ablegen; *a) Fit and correct putting on and removing of the mask;*	✓	
b) Hinweise zur Verwendung *b) Instruction on its use*	✓	

B Glossar / *Glossary*

2.2 Sichtprüfung / *Visual inspection*

Die Verpackung schützt die Maske nicht vor mechanischer Beschädigung und Verunreinigungen:

- Keine Verpackung vorhanden
- Verpackung ist ein offener und/oder nicht wiederverschließbarer Kunststoffbeutel
- Masken wurden lose in einem Pappkarton geliefert

The package does not protect the mask from mechanical damage and contamination:

- *No packaging supplied*
- *Packaging is an open and/or non-reclosable plastic bag*
- *Masks were delivered loose in a cardboard box*

2.3 Anlegeprüfung / *Donning test*

Offensichtliche Undichtigkeiten im Nasenbereich der CPA:

- Konstruktion Nasenbügel (Länge, Breite, Stärke, Material)
- Schnitt der Maske
- Verwendetes Maskenmaterial (Steifigkeit)
- Bänderung nicht stark genug

Obvious leaks in the area of the nose of the CPA:

- *Nose clip construction (length, width, thickness, material)*
- *Shape of the mask*
- *Mask material used (stiffness)*
- *Headgear not strong enough*

Offensichtliche Undichtigkeiten im Kinnbereich der CPA:

- Schnitt der Maske
- Verwendetes Maskenmaterial (Steifigkeit)
- Bänderung nicht stark genug
- Bänderung zu stark

Obvious leaks in the area of the chin of the CPA:

- *Shape of the mask*
- *Mask material used (stiffness)*
- *Headgear not strong enough*
- *Headgear too strong*

Offensichtliche Undichtigkeiten im Wangenbereich der CPA:

- Schnitt der Maske
- Verwendetes Maskenmaterial (Steifigkeit)
- Bänderung nicht stark genug

Obvious leaks in the area of the cheek of the CPA:

- *Shape of the mask*
- *Mask material used (stiffness)*
- *Headgear not strong enough*

Begründungen für nicht durchgeführte Prüfung:

- Starker Eigengeruch der Maske:
  Verwendete Materialien könnten ein Risiko für den Benutzer darstellen
- Partikel lösen sich von der Maske:
  Ablösende Partikel könnten ein Risiko für den Benutzer darstellen
- Atemwiderstand der Maske zu hoch (siehe 2.6):
  Zu hohe körperliche Belastung für den Benutzer

Reasons for not performed tests:

- *Strong inherent smell of the mask:*
  Materials used could be a risk for the user
- *Particles detach from the mask:*
  Detaching particles could be a risk to the user
- *Breathing resistance of the mask too high (see 2.6):*
  Too high physical stress for the user

2.4 **Durchlass des Filtermediums** / *Penetration of the filter medium*

Verwendetes Material ist im geprüften Aufbau nicht geeignet

(Materialwechsel kann negativen Einfluss auf **A**temwiderstand und/oder Anlegeversuch haben)

Material used is not suitable in the tested setup

(Change of material can have a negative influence on breathing resistance and/or donning test)

2.6 **Atemwiderstand** / *Breathing resistance*

Verwendetes Material erzeugt zu hohen Atemwiderstand

(Materialwechsel kann negativen Einfluss auf Filterdurchlass und/oder Anlegeversuch haben)

Material used is causing too high breathing resistance

(Change of material can have a negative influence on the penetration of the filter medium and/or donning test).

2.7 Kennzeichnung und Informationen des Herstellers / *Marking and manufacturer's information*

Name, Warenzeichen oder andere Angaben zur Identifikation des Herstellers (nicht bestanden):

- Keinerlei Angaben zum Hersteller
- Warenzeichen / Marke können keine eindeutige Informationen über die Produktionsstätte liefern (z.B. Markeninhaber ist nicht Hersteller und/oder hat mehrere Produktionsstätten)
- Angaben auf Maske, kleinster Verpackungseinheit und/oder Umverpackung unterscheiden sich von einander
- Nur Informationen zum Importeur verfügbar
- Informationen nicht in Deutsch oder Englisch verfügbar

Name, trademark or other information identifying the manufacturer (fail):

- *No information about the manufacturer*
- *Trademark / brand cannot provide clear information about the production site (e.g. brand owner is not the manufacturer and/or has several production sites)*
- *Information on mask, smallest packaging unit and/or packaging differ from each other*
- *Only information about the importer available*
- *Information not available in German or English*

Typidentische Kennzeichnung (Nummer, Modell oder Ähnliches) (nicht bestanden):

- KN95 und FFP2 (ohne jeden Zusatz) sind Klassifizierungen der Maske und keine Modellbezeichnungen (Beispiel für eine gültige Modellbezeichnung: Marke ABC Atemschutzmaske KN95/FFP2)
- Angaben auf Maske, kleinster Verpackungseinheit und/oder Umverpackung unterscheiden sich von einander
- Informationen nicht in Deutsch oder Englisch verfügbar

Marking identifying the type (number, model or similar) (fail):

- *KN95 and FFP2 (without any addition) are classifications of the mask and not type description (Example of a valid type description: Brand ABC respiratory mask KN95/FFP2)*
- *Information on mask, smallest packaging unit and/or packaging differ from each other*
- *Information not available in German or English*

Sitz sowie richtiges An- und Ablegen (nicht bestanden):

- Keinerlei Angaben
- Vorhandene Piktogramme nicht ausreichend
- Beschreibung zum An- und Ablegen der Maske nicht passend zum Maskentyp
- Beschreibung zum An- und Ablegen der Maske nicht vollständig/nicht eindeutig
- Informationen nicht in Deutsch oder Englisch verfügbar

Fit and correct putting on and removing of the mask (fail):

- *No information*
- *Existing pictograms not sufficient*
- *Description for putting on and removing of the mask not suitable for the mask type*
- *Description for putting on and removing of the mask not complete/not clear*
- *Information not available in German or English*

Hinweise zur Verwendung (nicht bestanden):

- Falsche, irreführende oder nicht validierte Angaben zur Wiederverwendbarkeit, Verwendungsdauer und Haltbarkeit der Maske
- Aussage: „Maske kann gereinigt werden"
- Gefährliche Aussagen zum Verwendungsbereich

Instructions for use (fail):

- *Incorrect, misleading or non-validated information on the reusability, duration of use and durability of the mask*
- *Statement: „Mask can be cleaned"*
- *Dangerous statements regarding the scope of use*