HATEX® GROUP

DR.FAMILY

JDF-01

FFP2 Mask

CE 2163 & DEKRA

EN149:2001+A1:2009


DR.FAMILY®
FFP2 NR - Maske
Faltbare Partikel - Atemschutzmaske
5 lagig
20 Stück
x 20
CE 2163
Standard EN149:2001+A1:2009
Bedienungsanleitung Fitting Instructions
Hinweis zur Verwendung:
NOTICE FOR USE:


DR.FAMILY®
FFP2 NR - Maske
5 lagig
Faltbare Partikel - Atemschutzmaske
Nicht medizinisch EN149:2001+A1:2009
• Hohe Filtrationseffizienz
• Geringer Atemwiderstand
• Bequem zu tragen
x 20
Mit Maskenhalter
20 Stück
EINZELVERPACKT
CE 2163
Standard:EN149:2001+A1:2009

FFP2 NR Maske

Model: JDF-01

SEE INFORMATION SUPPLIED BY THE MANUFACTURER

Nicht medizinisch EN149:2001+A1:2009
NON MEDICAL EN149:2001+A1:2009

⚠ WICHTIG:

Die Atemschutzmaske FFP2 Schützt Vor Pollen,Viren Und Industriestaub.

⚠ IMPORTANT:

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

ANWENDUNG:

Die Maske wird in der Schutzindustrie bei Staubentwicklung, während des Baus zur Staubverhütung, beim Metallguss, Steinabbau, in der Elektronik, Pharmazie, derphysikalischen Verarbeitung und beim Schleifen verwendet und bietet einen guten Schutz gegen Sandstürme, Dunst und PM2.5. Kann wirksam vor Pollenallergien, Virusübertragung usw. schützen.

APPLICATION:

It is used in the Protection industry for dust generation during construction, dust prevention, metal casting, stone mining, electronics, pharmaceutical, physical processing and grinding, which has good protection against sandstorms, haze and PM2.5. Can effectively protect pollen allergy, virus transmission, etc.

VERFALLSDATUM:

- Lagertemperatur: -20~38°C,
- Lagerfeuchtigkeit ≤ 80%,
- Haltbarkeit: 2 Jahre in, trockenen Innenräumen.

EXPIRATION DATE:

- The storage temperature is -20~38°C ,
- The storage is moderate ≤ 80%,
- The validity period is 2 year in the dry indoor environment.

FABRIK / MANUFACTORY:

Producer:Jinhua Jiadaifu Medical Supplies Co.,Ltd
Address: Dongxi Industrial Zone, Bailongqiao Town,Wucheng District, Jinhua City, Zhejiang Province,China

Importeur:
HATEX AS GmbH & Co.KG
Jakob-Kaiser-Str. 12
47877 Willich,Germany
info@hatex24.de

Artikelnummer: 50095

4 047125 500950

JDFS20201220-1

Bedienungsanleitung Fitting instructions

- Nehmen Sie die Maske heraus und öffnen Sie beide Seiten.
- Take out the mask and open both sides.

- Drücken Sie die Atemschutzmaske mit dem Bügel auf dem Nasenrücken gegen Ihr Gesicht. Positionieren Sie die elastischen Bänder hinter den Ohren.
- Press the mask against your face with the nose clip on the bridge of your nose. Position elastic belts to the back of ears.

- Formen Sie den Bügel mit beiden Händen in die Form Ihrer Nase.
- Shape the nose clip into the shape of your nose with both hands.

- Testen Sie die Passform. Nehmen Sie beide Hände über die Atemschutzmaske und atmen Sie kräftigaus. Wenn Luft um Ihre Nase strömt, ziehen Sie den Bügelfester.
- Test the correct fit. Put both hands over the respirator and exhale forcefully. When air flows out around your nose, press the nose clip tighter.

Hinweis zur Verwendung:

- Bitte verwenden Sie dieses Produkt nicht in der Nähe einer Feuerquelle.
- Aufgrund persönlicher Unterschiede kann Nebel in den Augen auftreten. Achten Sie daher beim Fahren besser darauf.
- Da es sich bei diesem Produkt um eine Einweg-maske handelt, kann es nicht durch Waschen wiederverwendet werden.
- Von hohen Temperaturen und Luftfeuchtigkeit fernhalten und an einem sauberen Ort aufbewahren.
- Verwenden Sie einzeln verpackte Produkte, sobald diese ausgepackt sind.

NOTICE FOR USE:

- Please do not use this product near Fire sources.
- Due to personal differences fog may appear in the eyes, so please pay more attention when driving.
- As this product is a disposable mask, it cannot be reused through washing.
- Keep it away from high temperature and humidity, and keep it in a clean place.
- Use individually packaged products as soon as they are unpacked.

Production date: 2021-01-02
Produktionsdatum:

Expiration date: 2023-01-01
Verfallsdatum:


DR.FAMILY®
FFP2 NR - Maske
Faltbare Partikel - Atemschutzmaske
Nicht medizinisch EN149:2001+A1:2009
• Hohe Filtrationseffizienz
• Geringer Atemwiderstand
• Bequem zu tragen


DR.FAMILY®
FFP2 NR - Maske
Faltbare Partikel - Atemschutzmaske
Nicht medizinisch EN149:2001+A1:2009
• Hohe Filtrationseffizienz
• Geringer Atemwiderstand
• Bequem zu tragen
5 lagig
5 layers
FFP2 NR Mask
Foldable Particulate Respirator
NON MEDICAL EN149:2001+ A1:2009
• High filtration efficiency
• Low respiratory resistance
• More comfortable to wear
x 1
Mit Maskenhalter
Incl. Mask Mate - Belt Extension Kit
1 Stück
1 PC
CE 2163
Standard:EN149:2001+A1:2009
Model: JDF-01

HATEX GROUP

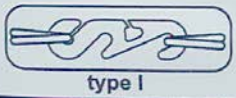
Bedienungsanleitung
Fitting instructions

- Nehmen Sie die Maske heraus und öffnen Sie beide Seiten.
- Take out the mask and open both sides.

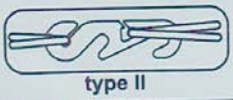
- Drücken Sie die Atemschutzmaske mit dem Bügel auf dem Nasenrücken gegen Ihr Gesicht. Positionieren Sie die elastischen Bänder hinter den Ohren.
- Press the mask against your face with the nose clip on the bridge of your nose. Position elastic belts to the back of ears.

- Formen Sie den Bügel mit beiden Händen in die Form Ihrer Nase.
- Shape the nose clip into the shape of your nose with both hands.

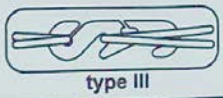
- Testen Sie die Passform. Nehmen Sie beide Hände über die Atemschutzmaske und atmen Sie kräftig aus. Wenn Luft um Ihre Nase strömt, ziehen Sie den Bügelfester.
- Test the correct fit. Put both hands over the respirator and exhale forcefully. When air flows out around your nose, press the nose clip tighter.



type I



type II



type III

for single use only

do not use if package is damaged

keep away from sunlight

read the instructions for use enclosed

maximum relative humidity of storage conditions

The temperature range of storage conditions

Hinweis zur Verwendung:

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- Aufgrund persönlicher Unterschiede kann Nebel in den Augen auftreten. Achten Sie daher beim Fahren besser darauf.
- Da es sich bei diesem Produkt um eine Einweg maske handelt, kann es nicht durch Waschen wiederverwendet werden.
- Von hohen Temperaturen und Luftfeuchtigkeit fernhalten und an einem sauberen Ort aufbewahren.
- Verwenden Sie einzeln verpackte Produkte, sobald diese ausgepackt sind.

NOTICE FOR USE:

- Please do not use this product near Fire sources.
- Due to personal differences fog may appear in the eyes, so please pay more attention when driving.
- As this product is a disposable mask, it cannot be reused through washing.
- Keep it away from high temperature and humidity, and keep it in a clean place.
- Use individually packaged products as soon as they are unpacked.

FABRIK / MANUFACTORY:
Producer:Jinhua Jiadaifu Medical Supplies Co.,Ltd
Address:Dongxi Industrial Zone,Bailongqiao Town,Wucheng District, Jinhua City,Zhejiang Province,China.

Importeur:
HATEX AS GMBH & Co.KG
Jakob-Kaiser-Str. 12, 47877 Willich, Germany
info@hatex24.de

Production date: Produktionsdatum: **2021-01-02**
Expiration date: Verfallsdatum: **2023-01-01**

Artikelnummer: 50095

4 047125 500950
JDFS20201220-1

DR.FAMILY

JDF-01

• Art.-Nr.: 50095	
• FFP2 Mask:	20 PCS
• Mask Kit:	20 PCS
• Instruction manual:	1 PC
• Qualified Certificate:	1 PC

4 047125 500950


DR.FAMILY
EN149:2001+A1:2009
JDF-01 FFP2 NR
CE 2163

HATEX GROUP

DR.FAMILY®

Jinhua Jiadaifu Medical Supplies Co.,Ltd

Brand Authorization Certification

This is to certify that **HATEX AS GmbH & Co. KG**, with office address at **Jakob-Kaiser-Str. 12, 47877 Willich, Germany** , was officially authorized to sales the brand name " DR.FAMILY® " of Filtering half mask (FFP2 NR) Mask in European market.

Authorizing Party: 金华家大夫医护用品有限公司 Jinhua Jiadaifu Medical Supplies Co.,Ltd

Jinhua Jiadaifu Medical Supplies Co.,Ltd

Address:Dongxi Industrial Zone, Bailongqiao Town, Wucheng District, Jinhua City,Zhejiang Province,China.

Signature : 唐宇帆

Title: General manager

Date:Nov. 25th, 2020

EU- Konformitätserklärung

Diese Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers ausgestellt:

Hersteller:	Jinhua Jiadaifu Medical Supplies Co., Ltd.
Adresse:	Dongxi industrial zone, Bailongqiao Town, Wucheng District, Jinhua City, Zhejiang Province, China.
Produktname:	Halbmaske, filternd (FFP2 NR)
Modell / Seriennummer:	JDF - 01
Technische Referenz:	EN 149:2001 + A1:2009 / Atemschutzeinheit, Halbmaske zum Schutz gegen Partikel, Prüfkennzeichen
Anwendbare Vorschriften:	PPE (EU) 2016/425
Prüfstelle zur Prüfung gemäß EU - Vorschriften Baumusterprüfung (Modul B):	Universalzertifikat - NB 2163 Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44/84 Yukari Dudullu Umraniye- Istanbul – TURKEY T:+90 216 455 80 80
Prüfstelle zur Prüfung gemäß EU – Vorschriften Baumusterprüfung (Modul C2):	Universalzertifikat – NB 2163 Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44 / 84 Yukari Dudullu Umraniye – Istanbul – TURKEY T:+90 216 455 80 80
Prüfstelle zur Prüfung gemäß EU – Vorschriften Baumusterprüfung (Modul D):	Universalzertifikat – NB 2163 Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44 / 84 Yukari Dudullu Umraniye – Istanbul – TURKEY T:+90 216 455 80 80
Zertifikat Nummer:	2163-PPE-724

Der beschriebene Gegenstand der Erklärung/ Das Produkt entspricht den einschlägigen Harmonisierungsrechtsvorschriften der Union

Internet: shop.hatex24.de - Rubriken - Zertifikate Masken

Hersteller: Jinhua Jiadaifu Medical Supplies Co., Ltd.
Datum: 30th November 2020
Position: Vorsitzende
Unterschrift: Tang Yufan

金华家大夫医护用品有限公司
Jinhua Jiadaifu Medical Supplies Co.,Ltd

Importeur: HATEX AS GmbH& Co.KG
Datum: 30.11.2020
Position: Geschäftsführer
Unterschrift: Rüdiger Grommes

EU- Konformitätserklärung

Hatex AS GmbH & Co. KG
Jakob-Kaiser-Str. 12
47877 Willich
Germany

Email: info@hatex24.de

www.hatex24.de

Diese Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers ausgestellt:

Hersteller:	Jinhua Jiadaifu Medical Supplies Co., Ltd.
Adresse:	Dongxi industrial zone, Bailongqiao Town, Wucheng District, Jinhua City, Zhejiang Province, China.
Produktname:	Halbmaske, filternd (FFP2 NR)
Modell / Seriennummer:	JDF - 01
Technische Referenz:	EN 149:2001 + A1:2009 / Atemschutzeinheit, Halbmaske zum Schutz gegen Partikel, Prüfkennzeichen
Anwendbare Vorschriften:	PPE (EU) 2016/425
Prüfstelle zur Prüfung gemäß EU - Vorschriften Baumusterprüfung (Modul B):	Universalzertifikat - NB 2163 Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44/84 Yukari Dudullu Umraniye- Istanbul – TURKEY T:+90 216 455 80 8
Prüfstelle zur Prüfung gemäß EU – Vorschriften Baumusterprüfung (Modul C2):	Universalzertifikat – NB 2163 Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44 / 84 Yukari Dudullu Umraniye – Istanbul – TURKEY T:+90 216 455 80 80
Prüfstelle zur Prüfung gemäß EU – Vorschriften Baumusterprüfung (Modul D):	Universalzertifikat – NB 2163 Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44 / 84 Yukari Dudullu Umraniye – Istanbul – TURKEY T:+90 216 455 80 80
Zertifikat Nummer:	2163-PPE-724

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Hersteller: Jinhua Jiadaifu Medical Supplies Co., Ltd.
Datum: 30th November 2020
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金华家大夫医护用品有限公司
Jinhua Jiadaifu Medical Supplies Co.,Ltd

Importeur: HATEX AS GmbH& Co.KG
Datum: 30.11.2020
Position: Geschäftsführer
Unterschrift: Rüdiger Grommes

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*	3417162.20-CPA
Prüfgegenstand *Test subject*	Corona SARS-CoV-2 Atemschutzmaske *Corona SARS-CoV-2 respiratory protective mask*
Modell *Type*	DR.FAMILY Disposable Non-medical Face Mask
Hersteller *Manufacturer*	Jinhua Jiadaifu Medical Supplies Co., Ltd Dong xi industrial zone, Bailongqiao Town, Wucheng District, Jinhua City, Zhejiang Province, China
Importeur *Importer*	Jinhua Jiadaifu Medical Supplies Co., Ltd Dong xi industrial zone, Bailongqiao Town, Wucheng District, Jinhua City, Zhejiang Province, 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.

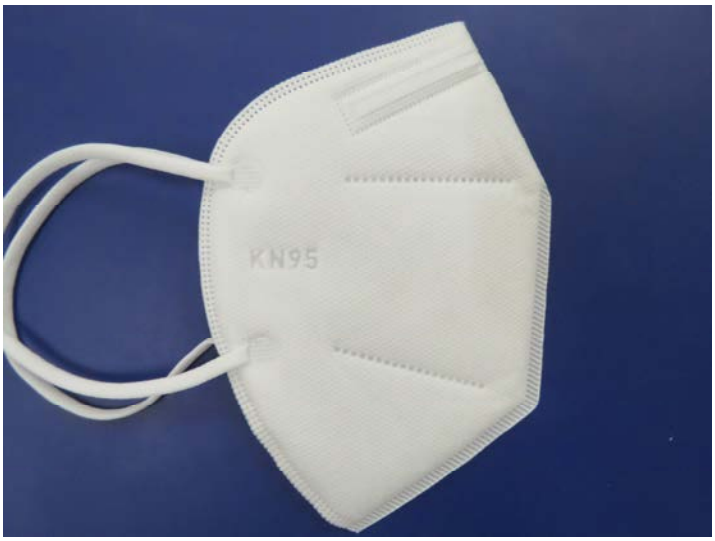
Diese Bewertung ist gültig vom 02.07.2020 bis 02.07.2021.
This evaluation of conformity is valid from 2020-07-02 until 2021-07-02.

DEKRA Testing and Certification GmbH
Bochum, 2020-07-02

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

DR.FAMILY Disposable Non-medical Face Mask



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. 3417162.20-CPA

Prüfgegenstand *Testsubject*	Corona SARS-CoV-2 Atemschutzmaske *Corona SARS-CoV-2 respiratory protective mask*
Modell *Type*	DR.FAMILY Disposable Non-medical Face Mask
Hersteller *Manufacturer*	Jinhua Jiadaifu Medical Supplies Co., Ltd Dong xi industrial zone, Bailongqiao Town, Wucheng District, Jinhua City, Zhejiang Province, 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 den Corona SARS-CoV-2 Prüfanforderungen. *The pandemic respiratory protective mask does meet the Corona SARS-CoV-2 test requirements.*
Datum *Date of issue*	01.07.2020

Dieser Bericht besteht aus 15 Seiten. *This report consists of 15 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*	21/04/2020
Auftraggeber *Applicant*	Jinhua Jiadaifu Medical Supplies Co., Ltd Dong xi industrial zone, Bailongqiao Town, Wucheng District, Jinhua City, Zhejiang Province, China
Importeur *Importer*	Jinhua Jiadaifu Medical Supplies Co., Ltd Dong xi industrial zone, Bailongqiao Town, Wucheng District, Jinhua City, Zhejiang Province, China
Eingang der Prüfmuster *Date of receipt of test item*	18/06/2020
Prüfzeitraum *Date (s) of performance of tests*	19/06/2020 – 29/06/2020
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*	✓		

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*

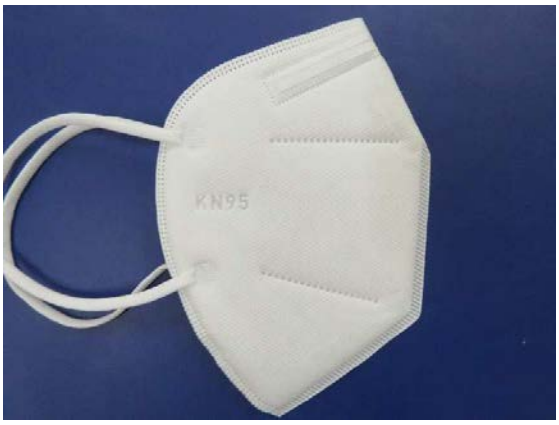
Die in diesem Bericht aufgeführten Ergebnisse beziehen sich ausschließlich auf die untersuchten Prüfmuster.
The results listed in this report refer only to the tested samples.
Für die Prüfung wurden folgende Dokumente zugrunde gelegt:
The following documents were taken as a basis for the tests:

1	Verpackung / *packaging*
2	Gebrauchsanweisung / *user manual*

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

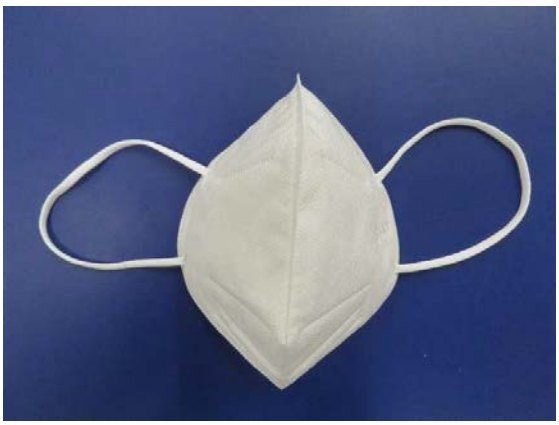
Verpackung / *Packaging*

Gebrauchsanweisung / *User manual*



Seitenansicht / *Side view*

Seitenansicht / *Side view*



Frontansicht / *Front 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 %	0,07
02	T.C. + S.W.		0,09
03	T.C. + S.W.		0,08

[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 Ausatemventil. *The CPA does not include an exhalation valve.*	**bestanden** *pass*	**nicht bestanden** *fail*
		✓	

2.6 **Atemwiderstand** / *Breathing resistance*

Die Atemwiderstände gelten für CPA ohne Ventil.
The breathing resistance requirements apply to 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	1,7
05	T.C. + S.W.		1,7

[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	2,9
05	T.C. + S.W.		2,9

[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*

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NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-724

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

Jinhua Jiadaifu Medical Supplies Co., Ltd.
Dongxi Industrial Zone, Bailongqiao Town, Wucheng District, Jinhua City, Zhejiang 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: DR FAMILY **Model:** JDF-01
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 **09/06/2020** 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

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NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-724/01

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

Jinhua Jiadaifu Medical Supplies Co., Ltd.

Dongxi Industrial Zone, Bailongqiao Town, Wucheng District, Jinhua City, Zhejiang 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 Nr.	Date	Issuing NB Nr.
DR FAMILY / JDF-01	FFP2 NR	2163-PPE-724	09.06.2020	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 **09/06/2020** and will be valid for one year, until **08/06/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

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TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 09.06.2020 / 2163-PPE-724

Manufacturer: Jinhua Jiadaifu Medical Supplies Co., Ltd.

Address: Dongxi Industrial Zone, Bailongqiao Town, Wucheng District, Jinhua City, Zhejiang Province, China

This report is for the, given above, manufacturer prepared according to the test results obtained from BEFITLAB Test Technology Shanghai Co., Ltd. accredited by IAS (International Accreditation Service), signatory to ILAC MRA, with number TL-787 for the product identified below, dated 30.05.2020 with Serial Id BT20200622T based on EN 149: 2001 + A1: 2009 standard and the technical file dated 01 June 2020 Version 01 provided by the manufacturer. The sampling of the product is conducted under our supervision for testing from the manufacturing site of the cient.

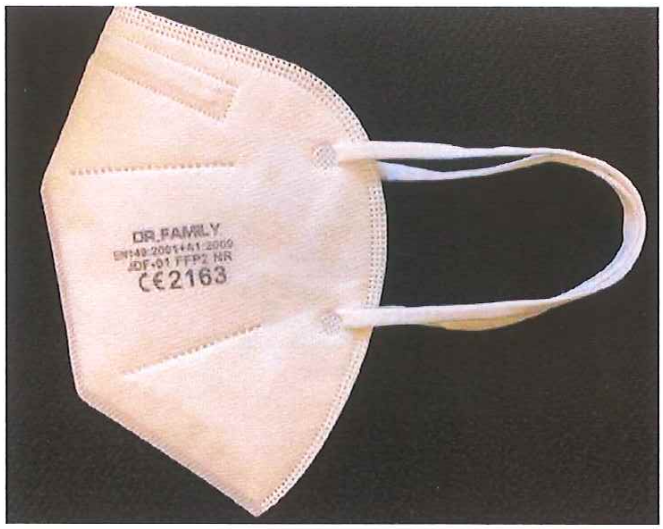
The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipment Regulation and found to be appropriate.

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

Trademark: DR FAMILY **Model:** JDF-01



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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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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 The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as; Filtering Efficiency and maximum Total Inward Leakage: Classified as FFP2 Mask is classified for single shift use, NR
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. The packaging design and the product is considered to withstand the foreseeable conditions of use based on the visual inspection results given in the test report.
Article **7.5**	**Material:** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results; It is understood it withstands handling and wear over the period for which the particle filtering half mask is designed to be used, it 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. The manufacturer declares that the materials used in manufacturing of the mask does not have an adverse affect to the health and safety of users. Based on the test results, the masks did not collapse when subject to simulated wearing and temarature conditioning. No nuisance situation is reported during the practical performance tests by human subjects.
Article **7.6**	**Cleaning and Disinfection:** Particle filtering half mask is **not** designed to be as re-usable. No cleaning or disinfection procedure provided by the manufacturer.
Article 7.7	**Practical Performance :** The test report indicates that the human subjects did not face any difficulty in performing the excercises while they were weared by the sample masks, in walking test or work simulation tests. The wearers did not report any failure by means of head harness / straps/ earloops comfort, security of fastenings and field of vision. Also no imperfactions reported during total inward tests about the comfort, field of vision and fastening issues.

Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result
2.Head harness comfort	2	0	Positive results are obtained from the test subjects **No imperfections**
3.Security of fastenings	2	0	
5.Field of vision	2	0	

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

Article 7.8	**Finish of Parts:** The test report states that the 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 an 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. The face dimensions of the subjects are also reported. The measurement details for each subject and for each excersize are available in the test report. All 50 exercise measurement results are smaller or equal to 11%, the values varies between 6,0 % and 8,6 %. At least 9 out of the 10 individual's arithmetic mean is smaller or equal to 8%, the values varies between 6,8 % and 8,1 %. **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.)	11	0,4		
(A.R.)	12	0,7		
(A.R.)	13	0,4	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 **FFP1, FFP2, FFP3** classes.
(S.W.)	14	0,3		
(S.W.)	15	0,6	FFP2 ≤ 6 %	
(S.W.)	16	0,6		
(M.S. T.C.)	17	0,7	FFP3 ≤ 1 %	
(M.S. T.C.)	18	0,4		
(M.S. T.C.)	19	0,3		

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.)	20	1,1		
(A.R.)	21	0,6		
(A.R.)	22	0,7	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 **FFP1, FFP2** classes.
(S.W.)	23	0,7		
(S.W.)	24	0,9	FFP2 ≤ 6 %	
(S.W.)	25	0,7		
(M.S. T.C.)	26	0,9	FFP3 ≤ 1 %	
(M.S. T.C.)	27	0,8		
(M.S. T.C.)	28	1,1		

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.)	29	Burn for 0s	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	**Passed**
(A.R.)	30	Burn for 0s		
(T.C.)	31	Burn for 0s		Filtering half masks fulfill requirements of the standard
(T.C.)	32	Burn for 0s		

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.)	33	0,36	0,36	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	**Passed**
(A.R.)	34	0,37			
(A.R.)	35	0,34			Filtering half masks fulfil requirements of the standard

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

Article 7.13

Head harness: In Practical Performance and TIL test reports no adverse effects have been reported for donning and remove of the mask also the results of these tests indicates that the ear loops / head harness are capable of holding the mask firmly enough.

Article 7.14

Field of vision: In Practical Performance report, no adverse effects were reported for the field of vision availability when the mask is weared.

Article 7.15

Exhalation Valve(s): The model under inspection have no valves.

Article 7.16

Breathing Resistance: Inhalation

The overall evaluation of the results gathered for 9 different samples 3 as received, 3 with temparature conditioning, 3 simulated wearing treatment 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. The measurement details for each single mask tested are available in the test report.

Passed.

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Article 7.17	**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 7.18	**Demountable Parts:** There are no demountable parts of the mask.
Article 8	**Testing:** All tests conducted according to Clause 8 of this standard is available in the test report and are evaluated in this report for qualification and classification of the mask.
Article 9	**Marking – Packaging:** Necessary markings are available on the product package (box). The manufacturer and its trademark is clearly visible. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the end date of shelf life, uisng and storage instructions and pictograms and CE mark are available on the product package. The above evaluation is based on the technical document for packaging and marking, for box design. Verified on the Annex 9.1 of the technical file. The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing JDF-01. The mask template (drawing) indicates that the mask will carry information about the manufacturer / trademark (DR FAMILY) of the manufacturer, Type of mask, the reference to EN 149+A1:2009 standard and classification including the re-usability of the mask. The manufacturer also printed CE mark with our Notified Body number. The mask do not have sub-assemblies. Even the tested sample by the laboratory do not carry necessary marking information as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production. Model drawing JDF-01exists in the technical file of the manufacturer, Annex 6 of technical file. .
Article 10	**Information to be supplied by the manufacturer:** In each of the smallest commercially available packaging of the product, implementation (installation instructions) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined. User instruction document in the technical file found to be appropriate, Annex 8. The manufacturer shall include this documented user information text in every smallest commertially available package.

PREPARED BY	APPROVED BY
Osman CAMCI PPE Expert	**Suat KAÇMAZ** General Manager

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UNIVERSAL CERTIFICATION CONFORMITY ASSESSMENT CO.
Tatlisu Mah. Arif Ay Sk. No:16/3 Umraniye, Istanbul / TURKEY

TEST REPORT

Report Date:04.05.2021
Report Number:04-2021-T0861

CLIENT and SAMPLE INFORMATION

TEST OWNER	Jinhua Jiadaifu Medical Supplies Co., Ltd.		
ADDRESS	Dongxi Industrial Zone, Bailongqiao Town, Wucheng District, Jinhua City, Zhejiang Province, China		
SAMPLE DESCRIPTION	Folding Type Protective Mask		
BRAND NAME – MODEL	Dr. Family FFP2 – JDF-01		
CASE NUMBER	CE-PPE-2121		
SAMPLE RECEIVE DATE	19.04.2021		
STARTING DATE	19.04.2021		
FINISH DATE	03.05.2021		
NUMBER OF SAMPLES	52	SAMPLE IDs:	1 – 52
AS RECEIVED SAMPLE NO	26-46, 50		
CONDITIONING SAMPLE NO	Simulated Wearing Treatment	1-2-3-4-5-6-7-8-9 (As Received)	
	Temperature Conditioning (T.C.)	10-11-12-13-14-15 (Sample after test of Mechanical Strength)	
		16-17-18-19-20-21-22-23-24-25-51 (As Received)	
	Mechanical Strength	10-11-12-13-14-15-52 (As Received)	
	Flow Conditioning (Only for particle filtering half masks with valve.)	47 (As Received) 48-49 (Sample after test of Temperature conditioning)	

NOTE 1

The results given in this test report belongs to the samples tested. The report content cannot be recreated partially without the written consent of UNIVERSAL CERTIFICATION.

NOTE 2

Requirements are taken from the EN 149: 2001 + A1: 2009 standard and the evaluation of results carried out according to these requirements.

NOTE 3

Information about conditioning;

Simulated wearing treatment:

A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask is mounted on a Sheffield dummy head. For testing, a saturator was incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 ºC to allow for the cooling of the air before it reaches the mouth of the dummy head. The air saturated at (37 ±2) ºC at the mouth of the dummy head.
In order to prevent excess water spilling out of the dummy's mouth and contaminating the particle filtering half mask the head inclined so that the water runs away from the mouth and is collected in a trap.
The breathing machine is brought into operation, the saturator switched on and the apparatus allowed to stabilize. The particle filtering half mask under the mounted on the dummy head. During the test time at approximately 20 min intervals the particle filtering half mask completely removed from the dummy head and refitted such that during the test period it is period it is fitted ten times to the dummy head.

Temperature conditioning (T.C.):

Exposed the particle filtering half masks to the following thermal cycle:

a) *For 24 h to dry atmosphere of (70±3) ºC;*
b) *For 24 h to dry atmosphere of (-30±3) ºC;*
And allowed to return room temperature for at least 4 h between exposures and prior to subsequent testing.
The conditioning carried out in a manner which ensured that no thermal shock occurs.

Mechanical strength:

After the masks / strainers are removed from their packaging (if they have seals on them, they are not opened) they are placed in the wide channels on the upper table of the device horizontally and not touching each other.

The device set and operated to operate at 100 revolutions per minute and the conditioning time to be 20 minutes.

As a result of the experiment, it was checked that any deterioration in the masks / strainers or the disassembled parts have not loosened or separated in any way.

Flow conditioning:

A total of 3 valved particle filtering half masks tested , one as received and two temperature conditioned in accordance with temperature.

NOTE 4

Information about evaluation;

Passed	*Results are suitable to requirements.*
Failed	*Results are not suitable to requirements.*
N/A	*Results are not applicable to requirements.*

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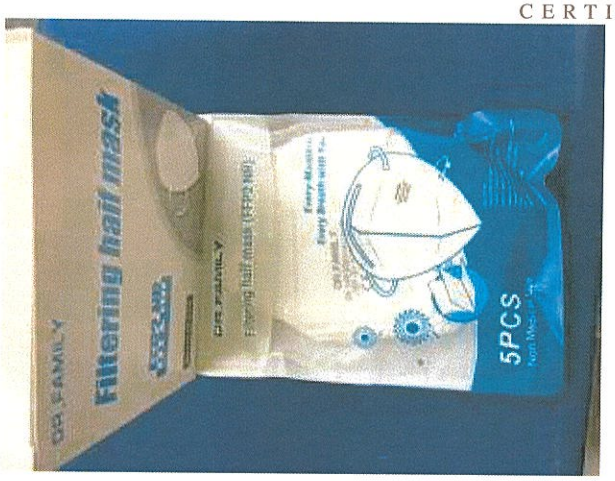
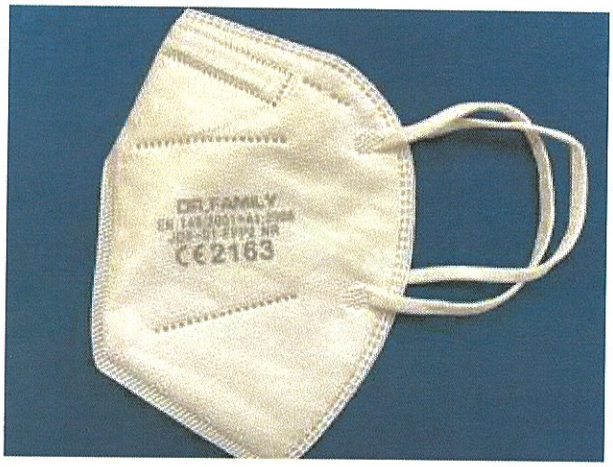
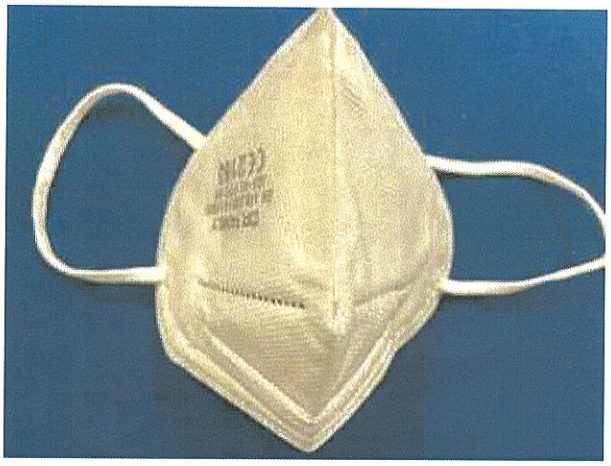
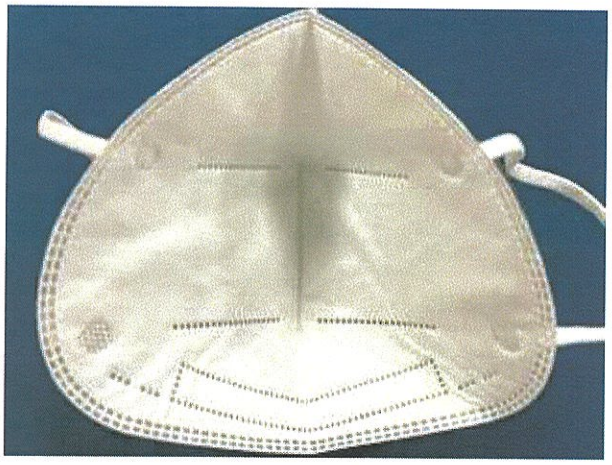
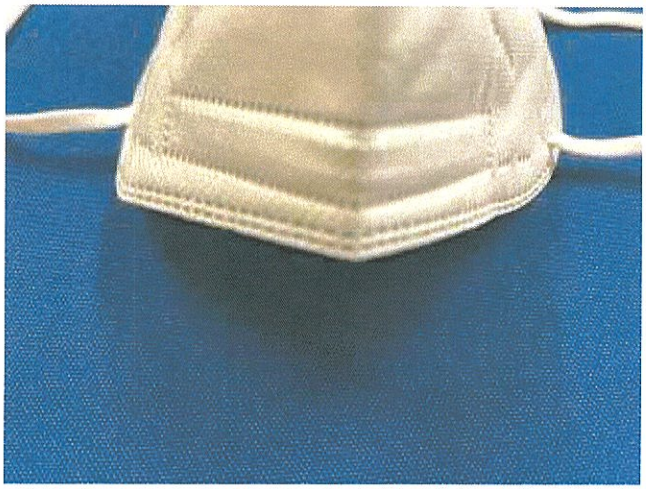
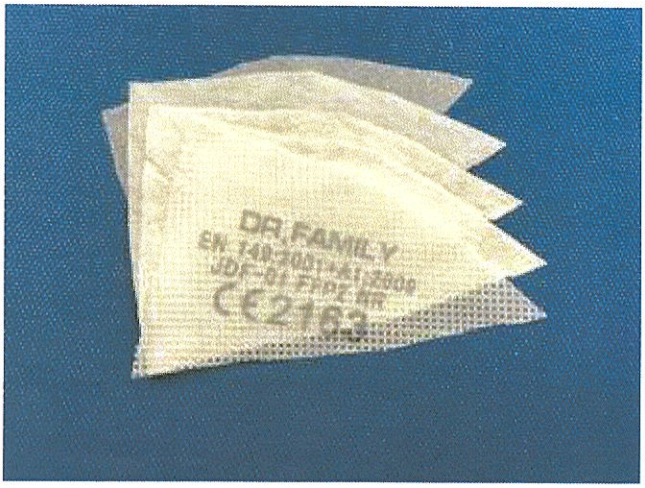

DR.FAMILY
Filtering half mask
5PCS


DR.FAMILY
CE2163








DR.FAMILY
CE2163

TEST RESULTS, REQUIREMENTS and EVALUATION

7.4 PACKAGING

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
The masks were packaged in sealed inside original box that gave some protection against mechanical damage or contamination before use.	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Passed

7.5 MATERIAL

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
Materials used are suitable to withstand handling and wear during the limited laboratory testing carried out.	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Passed
It did not constitute a hazard or nuisance for the wearer.	Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Passed
None of specimens conditioned suffered mechanical failure.	After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Passed
None of the specimens did not collapse after conditioning.	When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Passed

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7.6 CLEANING AND DISINFECTING

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
This analysis is not applicable because the masks are single use.	If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	N/A

7.7 PRACTICAL PERFORMANCE

Test Method: EN 149:2001 + A1:2009

The test results obtained are given in the tables as follows ,

Number of sample : 29 (A.R)[1], 30 (A.R)

ASSESSED ELEMENTS	POSITIVE ASSESSMENT	NEGATIVE ASSESSMENT	RESULTS	REQUIREMENTS	EVALUATION
The face piece fitting	2	0	No imperfections.	Filtering half masks should not have imperfections related to wearer's acceptance.	Passed
Head harness comfort	2	0			
Security of fastenings	2	0			
Field of vision	2	0			

[1]: *As received*

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7.8 FINISH OF PARTS

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
None of the specimens used in laboratory have no sharp edges or burrs.	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Passed

7.9.1 TOTAL INWARD LEAKAGE

Test Method: EN 149:2001 + A1:2009

REQUIREMENTS	EVALUATION
The total inward leakage consists of three components: face seal leakage, exhalation value leakage (if exhalation value fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual results shall be not greater than: 25 % for FFP1, 11 % for FFP2, 5 % for FFP3 and in addition at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall not be greater than: 22 % for FFP1, 8 % for FFP2, 2 % for FFP3	Passed Qualifies FFP1, FFP2

The test results obtained are given in the tables as follows,

TEST SUBJECT	NO OF SAMPLE	CONDITION	1. WALK (%)	HEAD SIDE/ SIDE (%)	HEAD UP/DOWN (%)	TALK (%)	2. WALK (%)	AVERAGE (%)
Z.Y	31	A.R.	1,43	1,05	0,90	0,80	1,07	1,05
K.D	32	A.R.	3,06	2,33	2,33	3,04	2,45	2,64
Y.A	33	A.R.	3,01	3,93	3,99	3,72	2,09	3,35
S.G	34	A.R.	1,84	2,34	2,27	2,53	2,23	2,24
U.A	35	A.R.	2,83	2,69	2,63	2,58	3,41	2,83
C.Y	16	T.C.	3,51	4,21	4,32	4,20	3,98	4,04
F.D	17	T.C.	3,10	3,48	3,34	2,08	4,87	3,37
E.C	18	T.C.	2,87	2,42	3,81	3,09	4,78	3,40
U.E	19	T.C.	3,24	3,28	3,33	3,28	3,48	3,32
C.A	20	T.C.	3,94	4,38	3,88	4,44	3,09	3,94

All of the 50 individual exercise results were not greater than 11 %
All of the 10 individual wearer arithmetic means were not greater than 8 %

The information in the test subject column is the initial of the candidates who performed the test.

***1.Walk**: walking for 2 min without head movement or talking;*

***Head side/side:** walking turning head from side to side (approximately 15 times), as if inspecting the walls of a tunnel for 2 min;*

***Head up/down:** walking and moving head up and down (approximately 15 times), as if inspecting the ceiling and floor for 2 min;*

***Talk:** walking and reciting the alphabet or an agreed text out loud as if communicating with a colleague for 2 min;*
***2.Walk:**: walking for 2 min without head movement or talking*

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Test Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
K.D	125	145	115	75
Z.Y	145	155	135	75
Y.A	135	145	105	55
B.K	125	145	125	75
S.G	135	145	125	75
F.D	135	155	135	65
E.C	135	165	125	60
C.A	140	170	160	70
U.E	115	165	115	65
C.Y	125	140	13	65

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7.9.2 PENETRATION OF FILTER MATERIAL

Test Method: EN 149:2001 + A1:2009

The test results obtained are given in the tables as follows,

NO. OF SAMPLE	CONDITION	RESULTS Penetration of **Sodium Chloride** in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	REQUIREMENTS	EVALUATION
36	As received	0,21	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Qualifies FFP1, FFP2, FFP3
37		0,24		
38		0,21		
1	Simulated wearing treatment	0,58		
2		0,63		
3		0,48		
10	Mechanical strength + Temperature conditioned	0,33		
11		0,21		
12		0,29		

Results for samples 10,11 and 12 is taken by exposure test. (the mask is loaded 120mg of NaCl)

The test results obtained are given in the tables as follows,

NO. OF SAMPLE	CONDITION	RESULTS Penetration of **Paraffin Oil** Mist in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	REQUIREMENTS	EVALUATION
39	As received	0,83	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Qualifies FFP1, FFP2, FFP3
40		0,36		
41		0,43		
4	Simulated wearing treatment	0,88		
5		0,92		
6		0,87		
13	Mechanical strength + Temperature conditioned	0,13		
14		0,78		
15		0,84		

Results for samples 13,14 and 15 is taken by exposure test. (the mask is loaded 120mg of Paraffin Oil)

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7.10 COMPATIBILITY WITH SKIN

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
No irritation or any other adverse effect to health or sensitivity reported by the subjects during the practical performance and TIL tests.	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	Passed

7.11 FLAMMABILITY

Test Method: EN 149:2001 + A1:2009

The test results obtained are given in the tables as follows,

NO. OF SAMPLE	CONDITION	VISUAL INSPECTION/ TIME (s)	REQUIREMENTS	EVALUATION
45	As received	0	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame.	Passed
46		0		
21	Temperature conditioned	0		
22		0		

7.12 CARBON DIOXIDE CONTENT OF THE INHALATION AIR

Test Method: EN 149:2001 + A1:2009

The test results obtained are given in the tables as follows,

NO. OF SAMPLE	CONDITION	RESULTS CO_2 Content Of The Inhalation Air [%] By Volume	RESULTS An Average CO_2 Content Of The Inhalation Air [%] By Volume	REQUIREMENTS	EVALUATION
26	As received	0,59	0,56	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume.	Passed
27		0,58			
28		0,50			

7.13 HEAD HARNESS

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
There is no problem with the head harness reported by the wearers during the practical performance test.	The head harness shall be designed so that the particle filtering half-mask can be donned and removed easily.	Passed
There is no problem with the head harness reported by the wearers during the practical performance test.	The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and capable of maintaining total inward leakage requirements for the device.	Passed

7.14 FIELD OF VISION

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
There were no adverse comments following practical performance tests.	The field of vision is acceptable if determined so in practical performance tests.	Passed

7.15 EXHALATION VALVE

Test Method: EN 149:2001 + A1:2009

NO. OF SAMPLE	RESULTS	REQUIREMENTS	EVALUATION
50 (As Received) 51 (Temperature conditioned) 52 (Mechanical strength conditioned)	No exhalation valve in tested samples.	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	N/A
	No exhalation valve in tested samples.	If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9	N/A
	No exhalation valve in tested samples.	Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30s.	N/A
	No exhalation valve in tested samples.	When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10N applied for 10s.	N/A

7.16 BREATHING RESISTANCE

Test Method: EN 149:2001 + A1:2009

The test results obtained are given in the tables as follows,

Inhalation Resistance

NO. OF SAMPLE	CONDITION	FLOW RATE 30 l/min [mbar]	REQUIREMENTS	FLOW RATE 95 l/min [mbar]	REQUIREMENTS	EVALUATION
42	As received	0,22	FFP1 ≤ 0,60 FFP2 ≤ 0,70 FFP3 ≤ 1,0	0,85	FFP1 ≤ 2,10 FFP2 ≤ 2,40 FFP3 ≤ 3,00	Passed Qualifies FFP1, FFP2, FFP3
43		0,27		0,94		
44		0,25		0,92		
7	Simulated wearing treatment	0,39		1,28		
8		0,46		1,55		
9		0,49		1,78		
23	Temperature conditioned	0,50		0,84		
24		0,46		1,63		
25		0,44		1,58		
47	Flow conditioned	-		-		
48		-		-		
49		-		-		

Exhalation Resistance

NO. OF SAMPLE	CONDITION	FLOW RATE	Facing directly [mbar]	Facing vertically upwards [mbar]	Facing vertically downwards [mbar]	Lying on the left side [mbar]	Lying on the right side [mbar]	REQUIREMENTS	EVALUATION
42	As received	160 l/min	1,22	1,21	1,23	1,22	1,23	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	Passed Qualifies FFP1,FFP2, FFP3
43			1,33	1,32	1,31	1,29	1,30		
44			1,24	1,25	1,25	1,23	1,25		
7	Simulated wearing treatment		1,88	1,87	1,85	1,89	1,88		
8			2,03	2,02	2,02	2,01	2,00		
9			2,45	2,44	2,45	2,46	2,43		
23	Temperature conditioned		2,42	2,40	2,44	2,38	2,40		
24			2,21	2,21	2,22	2,20	2,20		
25			2,17	2,13	2,19	2,21	2,22		
47	Flow conditioned		-	-	-	-	-		
48			-	-	-	-	-		
49			-	-	-	-	-		

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7.18 DEMOUNTABLE PARTS

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
No demountable part.	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	N/A

-End of Report-

TEST REVIEW

MURAT AYDEMİR

APPROVAL

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OSMAN CAMCI
Director

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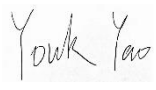
Test Report

Subject:	**Mechanical test for FFP2 NR MASK**
Product:	**FFP2 NR MASK**
Model No:	**JDF-01 / 50095**
Applicant:	**HATEX AS GmbH & Co. KG**
Applicant address:	**Jakob-Kaiser-Str. 12, 47877 Willich, Germany**
Manufacturer:	**Jinhua Jiadaifu Medical Supplies Co., Ltd**
Manufacturer address:	**Dongxi Industrial Zone, Bailongqiao Town, Wucheng District, Jinhua City, Zhejiang Province, China**
Requirement:	**test according to the following standard:** **EN 149:2001+A1:2009 Respiratory protective devices - filtering half masks to protect against particles - Requirements, testing, marking** **-clause7.9.1 total inward leakage**
Sample Receiving Date:	**Apr 15，2021**
Testing Period:	**Apr 15，2021 to Apr 25，2021**
Conclusion:	**Pass**

Signed for and on behalf of
DEKRA Testing and Certification (Shanghai) LTD.

Test Engineer: 
Date: **Apr. 25th2021**

Approver: 
Date: **Apr. 25th2021**

Attention: Please note that every statement made in this report is only valid for the samples tested and reported herein. This report shall not be reproduced except in full, without the written approval of the testing laboratory. If you have any comment on the test results, please contact us in writing in 15days after the issuing of report.

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Test Result

1. Respiratory protective devices - filtering half masks to protect against particles

With reference to EN 149:2001+A1:2009 Respiratory protective devices - filtering half masks to protect against particles - Requirements, testing, marking, the submitted samples were subjected to the following test:
Number of Sample Tested: twenty (20) Piece per style, Total one (1) styles.

Sample Description: White
Test Item particulars: Single Shift Particle Filtering half Mask
classes of device: FFP2
exhalation valve (S): No
inhalation valve (S): No
design to prevent against both solid & liquid aerosols: Yes
The environmental conditions of the testing in this report:
1) The ambient temperature to be tested shall be 25 °C unless otherwise specified:
2) temperature conditioned temperature adjustment
a) Set in a dry environment at 70°C for 24 hours
b) Set to -30°C for 24 hours
c) and return to room temperature for 4 hours between exposures and prior to subsequent testing

clause	Test item	Test result	Verdict
7.9.1	Leakage-Total inward leakage For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than 25 % for FFP1 11 % for FFP2 5 % for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22 % for FFP1 8 % for FFP2 2 % for FFP3.	Meet (See table 1, 2)	**P**

Abbreviation: **P**=**P**ass; **F**=**F**ail; **NA**=**N**ot **A**pplicable; **NC**=**N**ot **C**onducted; **NT= Not tested**

***** To be continued *****

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Table 1:

Exercises	E1 (%)	E2 (%)	E3 (%)	E4 (%)	E5 (%)	TIL (%)
As received	3.4	3.6	3.9	3.5	3.7	3.6
	0.7	1.0	1.6	3.1	1.8	1.6
	2.6	6.4	5.8	4.1	2.8	4.3
	1.2	3.5	4.9	4.1	2.5	3.2
	3.0	4.5	6.2	5.7	3.4	4.6
Temperature conditioned	1.6	2.5	4.7	4.1	2.0	3.0
	2.5	3.4	6.1	4.9	3.1	4.0
	2.1	4.2	5.7	5.1	3.2	4.1
	1.9	4.0	4.8	4.4	2.5	3.5
	3.0	4.5	6.7	6.1	3.2	4.7

Table 2- Facial Dimension

subject	Face length(mm)	Face width(mm)	Face depth(mm)	Mouth width(mm)
1	120	130	109	59
2	122	140	115	65
3	119	160	139	55
4	112	122	119	63
5	110	130	118	60
6	115	119	110	59
7	112	123	113	55
8	103	130	100	50
9	118	139	130	63
10	115	129	120	50

***** To be continued *****

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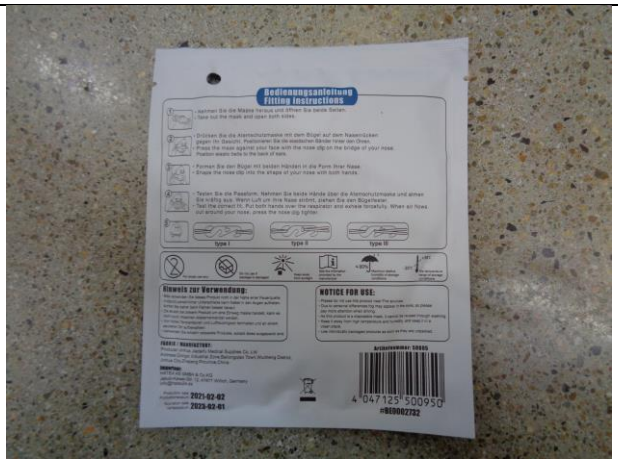
Test photos

	
Test photo 01: sample as received	Test photo 02:packaging
	
Test photo 03: packaging	Test photo 04: packaging

********End of Report********

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