

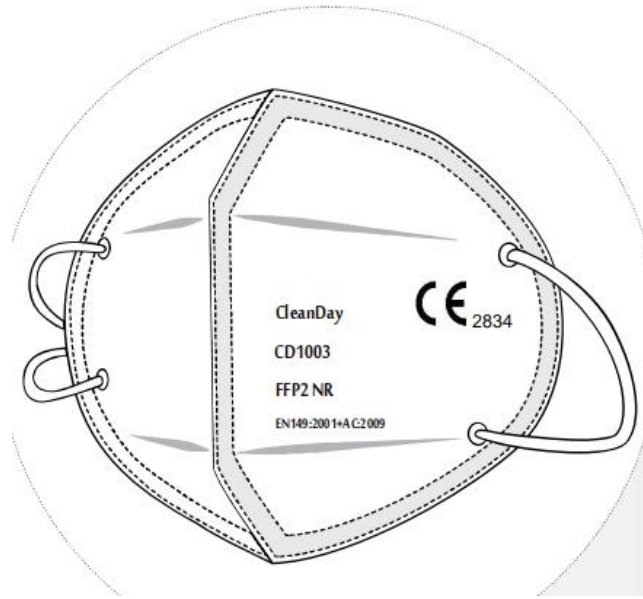
CleanDay

Particle Filtering Half Mask

Model :CD1003

EN 149:2001+AC:2009

Product pictures



CleanDay

Particle filtering half mask

Model: CD1003

FFP2 NR

EN 149:2001+A1:2009

Regulation(EU) 2016/425

CE 2834

Fitting Instruction

1. Hold the particle filtering half mask firmly.
2. Place under chin and press the mask freely against your face with the nose clip on the bridge of your nose. Pull the head harness behind the ears and attach the two straps with the clip behind the head.
3. Using both hands, mold the nose clip to the shape of nose.
4. To check for proper fit, cup both hands over the mask and exhale vigorously. If air leaks around the nose, tighten the nose clip, if air leaks around the edge, reposition the headharness for better fit.
5. Repeat adjustments until the mask is sealed properly.
6. This mask must only be used with the clip in place.

Lot No.:
MFG Date:
End of shelf life:

1PC

CleanDay

User Instructions

1. To protect your health and to prevent serious injury or death, it is important to read and follow all the instructions provided with the enclosed product. Please read all warning printed on the packaging box.
2. Please check prior to using to ensure:
The head harness is attached well;
The nose clip and sponge are attached properly on the mask.

Warning

1. This mask marked "NR", shall not be used for more than one shift.
2. Never substitute, modify, add, or omit parts in the configuration as specified by the manufacturer.
3. This mask offers protection against certain particulate contaminants but does not completely eliminate exposure to the risk of contracting disease or infection.
4. Do not use the particle half mask with facial hair or any other conditions that may prevent a good faceseal, the requirements of leakage will not be achieved.
5. Discard and replace the mask if:
 - a) The mask is removed whilst in the contaminated areas.
 - b) Clogging of the mask causes breathing difficulties.
 - c) The mask becomes damaged.

Limitation

- Do not use the respirator to enter or stay in a contaminated area under the following circumstances:
- a) Atmosphere contains less than 19.5% oxygen.
 - b) If you smell or taste contaminant.
 - c) For protection against gases or vapors.
 - d) Contaminants or their concentrations are unknown or immediately dangerous to life or health.
 - e) For sandblasting, paint-spray operations and asbestos treatment.
 - f) In explosive atmospheres.

Storage

The mask should not be removed from its package until it is required for use, and should be discarded after use.



Temperature range of storage conditions



Maximum relative humidity of storage conditions



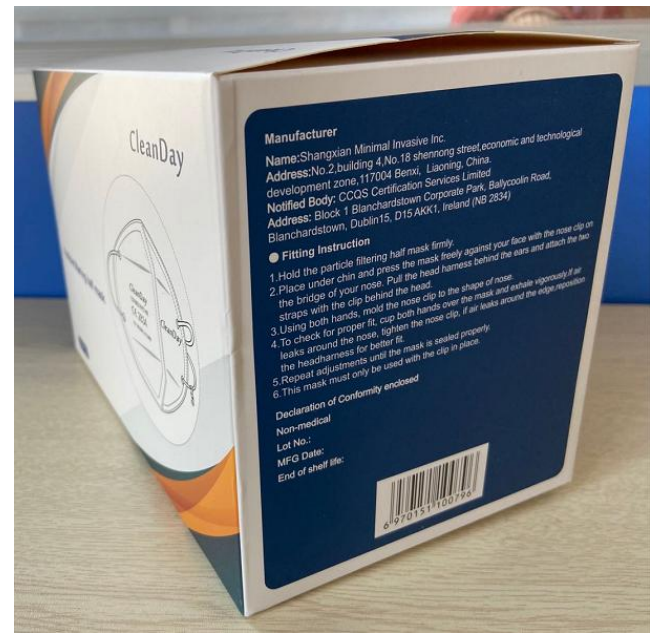
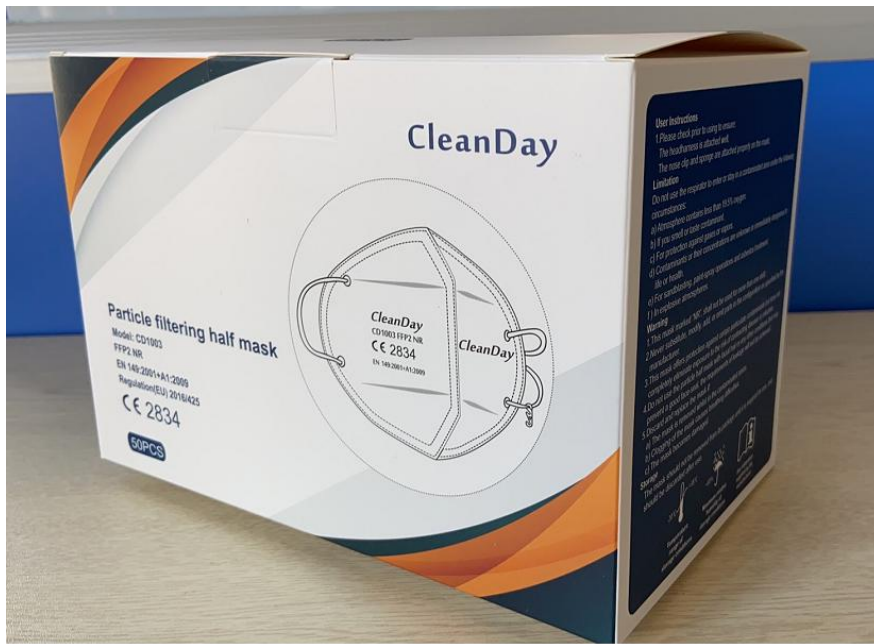
See information supplied by the manufacturer

Declaration of Conformity enclosed
Non-medical

Manufacturer:

Name: Shangxian Minimal Invasive Inc.
Address: No.2, building 4, No.18 shennong street,
economic and technological development zone,
117004 Benxi, Liaoning, China.

Notified Body: CCQS Certification Services Limited
Address: Block 1 Blanchardstown Corporate Park,
Ballycoolin Road, Blanchardstown, Dublin15,
D15 AKK1, Ireland (NB 2834)





Specifications

Without pallet:

Size of carton	Packing	Gorss weight	Measurement
70*24*32CM	1pcs / bag 50pcs / inner box 500pcs / outer carton	7kgs/carton	0.051CBM/carton

Wtih pallet:

Size of pallet	Packing	Gorss weight	Measurement
1.2*1.26*1.5m	20,000pcs/pallet	290kgs/pallet	2.27CBM/pallet

Business License & Production license


营业执照
(副本)

统一社会信用代码 91210500068340327C
码 (副本号: 1-1)

名称 沈阳尚贤医疗系统有限公司
类型 有限责任公司(法人独资)
住所 本溪高新技术产业开发区木兰路中国药都创新园B2-2区一层

法定代表人 李玉霞
注册资本 人民币贰仟万元整
成立日期 2013年06月06日
营业期限 自2013年06月06日至2028年06月05日
经营范围 医疗器械生产销售(具体经营范围以许可证为准);
医疗器械研发,科学仪器、电子产品、软件产品研发
与销售,自营和代理各类商品和技术进出口,但国家
限定公司经营或禁止进出口的商品和技术除外。(依
法须经批准的项目,经相关部门批准后方可开展经营
活动)。




登记机关 
2018年08月10日

提示:应当于每年1月1日至6月30日,通过企业信
用信息公示系统报送上一年度年度报告并公示。

医疗器械生产许可证

许可证编号: 辽食药械生产许20160013号

企业名称: 沈阳尚贤医疗系统有限公司
生产地: 本溪高新技术产业开发区木兰路中国药都创新园B2-2区一层, 本溪经济技术开发区神农大街18-4栋2号3层

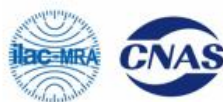
法定代表人: 李玉霞
生产范围:
2017年12月
核准生产第一类医疗器械
2018年04月06日

企业负责人: 李玉霞

住所: 本溪高新技术产业开发区木兰路中国药都创新园B2-2区一层
发证部门: 辽宁省药品监督管理局

有效期限: 至 2021年04月6日
发证日期: 2020年05月07日

国家药品监督管理局制



中国认可
国际互认
检测
TESTING
CNAS L1499

National Quality Supervision and Testing Center for Personal
Protective Equipment (Beijing)
(Testing Laboratory for Labour Protection Products of Beijing
Municipal Institute for Labour Protection)

No.55 Taoranting Street, Xicheng District, Beijing, China.
Phone: +86 10 63519250 +86 10 63520770 +86 10 83530311
Fax: +86 10 63519250 +86 10 63520770

The Testing Center is accredited for compliance with ISO/IEC 17025.

The results of tests, calibrations and/or measurements included in this document are traceable to Chinese/national standards.

CNAS is a signatory to the ILAC mutual recognition arrangement for the mutual recognition of the equivalence of testing, calibration and inspection reports.

TEST REPORT

Particulate respirator-half facepiece

EN 149: 2001 +A1: 2009 Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking

Product: Particle filtering half mask

Report No: 2020 (F) - 0179

Client: Shangxian Minimal Invasive Inc

Model (s): CD1003

Date(s) of tests: 2020.06.09-2020.06.26

DESCRIPTION OF SAMPLES

General Information	Classification	Main Components
Manufacturer	FFP2 NR	White folding mask
Manufacturer Address	Shangxian Minimal Invasive Inc 1 st Floor, Block B2-2, China medicine innovation park, Mulan road, Hi-tech development Zone, 117004 Benxi, Liaoning, China	

Signed:

Issued: 2020.6.28

陈倬为 Chen Zhuowei
Authorized Signatory, Lab Director

Page 1 of 10

Report No: 2020 (F) - 0179

Page 2 of 10

Conditions:

The test results presented in this report relate to the samples tested only.

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The authenticity of this test report and its contents can be verified by contacting the laboratory.

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Test Results

7.3 Visual inspection Not tested¹

The visual inspection shall include the marking and information supplied by the manufacturer.
Note1: As requested by the client, marking and information supplied by the manufacturer was not inspected.

7.4 Package Pass²

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.
Note2: In accordance with the requirement.

7.5 Material Pass³

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.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

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.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Note3: No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2.

7.6 Cleaning and disinfecting N/A⁴

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.

Note4: Single shift use only.

7.7 Practical performance Pass⁵

The particle filtering half mask shall undergo practical performance tests under realistic conditions.
Note5: No imperfections.

7.8 Finish of parts Pass⁶

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

Note6: No sharp edges or burrs.

7.9.1 Total inward leakage Pass⁷

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: 22% 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

Note7: FFP2 respirator. Test results are shown in Annex A Table 7.9.1-A&B.

7.9.2 Penetration of filter material Pass⁸

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

Sodium chloride test 95 l/min

Paraffin oil test 95 l/min

FFP1 ≤20%

≤20%

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FFP2 ≤6% ≤6%
 FFP3 ≤1% ≤1%

Note8: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.

7.10 Compatibility with skin Pass⁹

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.

Note9: No irritation or any other adverse effect to health.

7.11 Flammability Pass¹⁰

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

Note10: Test results are shown in Annex A Table 7.11.

7.12 Carbon dioxide content of the inhalation air Pass¹¹

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume)

Note11: Test results are shown in Annex A Table 7.12.

7.13 Head harness Pass¹²

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

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 be capable of maintaining total inward leakage requirements for the device.

Note12: Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the particle filtering half mask firmly.

7.14 Field of vision Pass¹³

The field of vision is acceptable if determined so in practical performance tests.

Note13: Pass the practical performance tests.

7.15 Exhalation valve N/A¹⁴

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

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.

Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

Note14: No exhalation valve.

7.16 Breathing resistance Pass¹⁵

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Note15: FFP2 respirator. Test results are shown in Annex A Table 7.16.

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7.17 Clogging

N/A¹⁶

7.17.2 Breathing resistance

Valved particle filtering half masks:

After clogging the inhalation resistances shall not exceed:

FFP1 : 4 mbar, FFP2 : 5 mbar, FFP3 : 7 mbar at 95L/min continuous flow

The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow

Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed:

FFP1 : 3 mbar, FFP2 : 4 mbar, FFP3 : 5 mbar at 95L/min continuous flow

7.17.3 Penetration of filter material

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note 6: Single shift use only.

7.18 Demountable parts

Pass¹⁷

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand

Note 7: In accordance with the requirement.

9 Marking

Not tested

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.1.2 Type-identifying marking.

9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.1.4 The number and year of publication of this European Standard.

9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.

9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.

9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.

9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.

9.2 Particle filtering half mask

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

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9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

End of Test Results

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Annex A: Summarization of Test Data

Table 7.9.1-A Inward leakage test data

Test specification: EN 149-2001 Clause 8.5

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Yi	1	A.R.	7.35	7.69	7.62	7.36	7.82	7.6
Gong	2	A.R.	7.27	7.44	7.57	7.60	7.72	7.5
Yu	3	A.R.	6.92	7.04	7.18	7.08	6.93	7.0
Hu	4	A.R.	7.37	7.55	7.49	7.60	7.77	7.6
Xu	5	A.R.	6.62	6.69	6.84	6.63	7.10	6.8
Deng	6	T.C.	5.13	5.51	5.49	5.54	5.44	5.4
Zhang	7	T.C.	6.37	6.49	6.39	6.39	6.38	6.4
Zhi	8	T.C.	5.75	5.81	6.23	5.76	6.18	5.9
Fang	9	T.C.	5.66	5.66	5.84	5.95	6.15	5.9
Lv	10	T.C.	8.79	9.34	8.97	8.83	8.82	8.9
All 50 individual exercise results were not greater than 11% 9 out of 10 individual wearer arithmetic means were not greater than 8%							Pass	

Table 7.9.1-B Facial dimension

Subject	Face length	Face Width	Face Depth	Mouth Width
Yi	120	130	109	59
Gong	122	140	115	65
Yu	119	160	139	55
Hu	112	122	119	63
Xu	110	130	118	60
Deng	115	119	110	59
Zhang	112	123	113	55
Liu	103	130	100	50
Zhi	118	139	130	63
Fang	115	129	120	50
Chen	116	150	132	56
Lv	110	121	110	53

Table -7.9.2 Penetration of filter material

Test specification: EN 149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assesment
Sodium chloride test	As received	11	0.414	Pass
		12	0.527	
		13	0.489	
	Simulated wearing treatment	14	0.733	
		15	0.616	
		16	0.662	
	Mechanical strength+ Temperature conditioned	17	0.925	
		18	0.877	
		19	0.918	
Paraffin oil test	As received	20	1.82	
		21	1.96	
		22	1.87	
	Simulated wearing treatment	23	2.18	
		24	2.49	
		25	2.32	
	Mechanical strength+ Temperature conditioned	26	2.74	
		27	2.62	
		28	2.78	
Flow conditioning: Single filter: 95.0 L/min				

Table 7.11 Flammability

Test specification: EN 149-2001 Clause 8.6

Condition	Sample No.	Result	Assessment
As received	29	Burn for 2 s	Pass
	30	Burn for 1 s	
Temperature conditioned	31	Burn for 1 s	
	32	Burn for 2 s	

Table 7.12 Carbon dioxide content of the inhalation air

Test specification: EN 149-2001 Clause 8.7

Condition	Sample No.	Result	Assessment
As received	33	0.42%	Mean value 0.4% Pass
	34	0.41%	
	35	0.42%	

Table 7.16 Breathing resistance (mbar)

Test specification: EN 149-2001 Clause 8.9

As received	Flow rate	36					37					38					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
Inhalation	30 l/min	0.4	0.5	0.5	0.5	0.6	0.4	0.6	0.5	0.5	0.5	0.4	0.5	0.4	0.5	0.6	
	95 l/min	1.4	1.5	1.6	1.6	1.6	1.5	1.6	1.6	1.5	1.6	1.4	1.5	1.5	1.4	1.5	
	Exhalation	1.60	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	
Simulated wearing treatment	Flow rate	39					40					41					
		30 l/min	0.5	0.6	0.6	0.4	0.6	0.5	0.4	0.4	0.4	0.5	0.5	0.6	0.4	0.5	0.5
		95 l/min	1.5	1.4	1.6	1.5	1.5	1.6	1.5	1.4	1.4	1.6	1.5	1.4	1.6	1.6	1.6
Temperature conditioned	Flow rate	42					43					44					
		30 l/min	0.5	0.5	0.6	0.5	0.6	0.5	0.4	0.4	0.4	0.6	0.4	0.5	0.4	0.6	0.6
		95 l/min	1.6	1.4	1.5	1.5	1.5	1.5	1.4	1.5	1.5	1.4	1.4	1.6	1.5	1.5	1.6
Exhalation	2.0	1.9	2.1	2.1	2.0	1.9	1.9	2.0	2.0	1.9	2.0	2.1	2.0	1.9	2.0		
Assessment		Pass															

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

End of Annex A

ANNEX B PHOTOS OF SAMPLES



End of Annex B



Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200416-261-01-9A

Certificate holder:	Shangxian Minimal Invasive Inc. 1st Floor, Block B2-2, China Medicine Innovation Park, Mulan Road, Hi-Tech Development Zone, 117004 Benxi, Liaoning, China
Product:	Particle Filtering Half Mask Detailed product description listed in the Annex
Model(s):	CD1003
Standard(s):	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
Issue date:	2020-09-08
Revision date:	2020-09-08
Expiry date:	2021-09-07

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the applicable Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425.

Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS Certification Services Limited for review.

CE marking shall not be applied until the requirements of all the PPE Regulation 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.

If the certified product is Category III then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.

This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.



Approved by Ireland Government as a Notified Body for CE Marking No.2834



CCQS Certification Services Limited

Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland

Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: verify@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.



Module B EU Type-Examination Certificate

Annex

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200416-261-01-9A

Applicable standards and specification:

EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Model reference	Product description
CD1003	Folding filtering half mask fitted with ear loops with head harness clip, no valves, internal metal nose clip Mask body color: White Classification: FFP2 NR Test report No.: 2020(F) - 0179

Certificate Revision	Revision date	Revision details
A	2020-09-08	Initial issue



CCQS Certification Services Limited

Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland

Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: verify@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.



Certificate of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

FPC Certificate No.: CE-PC-200416-261-FPC-A

Certificate holder: Shangxian Minimal Invasive Inc.
1st Floor, Block B2-2, China Medicine Innovation Park, Mulan Road, Hi-Tech Development Zone, 117004 Benxi, Liaoning, China

Manufacturing location: No.2, Building 4, No.18 Shennong Street, Economic and Technological Development Zone, 117004 Benxi, Liaoning, China

The scope of the certification for: **The manufacture of respiratory protective device**
See annex for articles covered by this certificate

Validity from: 2020-09-09

Revision date: 2020-09-09

To: 2021-09-08

CCQS Certification Services Limited in its role as a Notified Body for PPE Regulation, is monitoring that the manufacturer is producing PPE in conformity with the type described in the EU type-examination certificate and associated technical file and which satisfies the Essential Health and Safety Requirements of the Regulation. The equipment covered by this certificate is listed in the accompanying schedule. This certificate is not complete and has no validity without the accompanying schedule and revision index. The manufacturer is hereby authorized to affix our Notified Body number, 2834, to each item of PPE mentioned in the schedule which accompanies this certificate whilst this certificate remains valid. This certificate and the accompanying schedule remain the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.



Approved by Ireland Government as a Notified Body for CE Marking No.2834



CCQS Certification Services Limited

Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: verify@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.



Schedule of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

Schedule to CCQS FPC Certificate No.: CE-PC-200416-261-FPC-A

Product reference and description		Reference standard
Particle Filtering Half Mask	Model: CD1003	EN 149:2001+A1:2009

Certificate Revision	Revision date	Revision details
A	2020-09-09	Initial issue

This schedule has no validity without the accompanying certificate. This schedule and the accompanying certificate remain the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.



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