



## EU-Konformitätserklärung

*EU-Declaration of Conformity*

**Batch code**/Batch code

**Wir / we** *Cherry medical holding (Shenzhen) Co., Ltd.  
Room 602, Yuanling Building , No.2002,Hongli Road,  
Nantian Community,  
Yuanling Street,  
Futian District,  
Shenzhen,  
China*

**erklären in alleiniger Verantwortung, dass das Produkt**  
*declare under our sole responsibility that the product*



**Partikelfiltrierende Halbmaske QRYW202005**

*Filtering half mask QRYW202005*

**mit der EU-Baumusterprüfbescheinigung / Expertise**

*is in conformity with the EU-Type Examination Certificate / FI20/966583  
Expertise*

**ausgestellt von der notifizierten  
Stelle mit der Kenn-Nr.**

**SGS FIMKO OY,**

**Takomotie 8, FI-00380,**

*issued by the Notified Body*

**Helsinki,Finland**

with Identification No.

0598

mit den folgenden Richtlinien unter Anwendung der aufgeführten Normen übereinstimmt

and in compliance with the following directives by application of the listed standards

Name und Fundort der Verordnung <i>Name and Location of the Regulation</i>		Nummer sowie Ausgabedatum der Norm <i>Number and date of issue of standard</i>
(EU) 2016/425, ABl.Nr.L 81/51, 2016	persönliche Schutzausrüstungs- Verordnung <i>Personal Protective Equipment Regulation</i>	EN 149:2001 + A1:2009

Die PSA unterliegt folgendem Konformitätsbewertungsverfahren: Konformität mit dem Baumuster auf der Grundlage einer Qualitätssicherung bezogen auf den Produktionsprozess (Modul C2) unter Überwachung der notifizierten Stelle SGS FIMKO OY, mit der Kennnummer NB.0598.

*The PPE is subject to the following conformity assessment procedure: Conformity to type based on quality assurance of the production process (Module C2) under surveillance of the notified body SGS FIMKO OY,NB.0598.*

Shenzhen, 2020-12-28

Ort und Datum (jjjj-mm-tt)

Place and date (yyyy-mm-dd)



Cherry medical holding  
(Shenzhen) Co., Ltd.

# Cherry medical holding (shenzhen) Co.,Ltd.

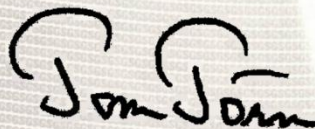
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Yuanfing Street,  
Futian District,  
Shenzhen,  
China

It is certified that the manufacturer's technical file and the PPE product detailed on page 2 have been assessed and found to be in accordance with

## Regulation (EU) 2016/425 Module B, EU type-examination

This certificate is valid from 15 September 2020 until 15 September 2025  
1. Certified since 15 September 2020

Authorised by



SGS FIMKO OY, Notified Body 0598  
Takomotie 8, FI-00380, Helsinki, Finland  
t +358 9 696 361 f +358 9 692 5474 www.sgs.com



**FINAS**  
Finnish Accreditation Service  
S003 (EN ISO/IEC 17065)

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## Cherry medical holding (shenzhen) Co.,Ltd.

### Regulation (EU) 2016/425 Module B, EU type-examination

Issue 1

PPE Product

CHERRY (logo) QRYW202005 particle filtering half mask, consisting of a white five layer (polypropylene/poly tetra fluoroethylene) disposable face mask, with aluminium nose clip, and polyester/spandex ear loop with plastic hook.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:

EN 149:2001+A1:2009 (Respiratory protective devices - filtering half masks to protect against particles) device classification: FFP2 NR.

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 19 (c) of the Regulation are implemented and maintained while the model is in production

Certification is based on technical file reference:

Filtering half mask/ QRYW202005, version 1, dated: 2020-08-04.

SGS Reference Number UK/CRS 241718.

This certificate remains the property of SGS Fimko Oy to whom it must be returned on request

Certificate CN20/42384

The management system of

# Cherry Medical Holding (Shenzhen) Co., Ltd.

Room 602, Yuanling Building, No. 2002, Hongli Road,  
Nantian Community, Yuanling Street, Futian District, Shenzhen, China

has been assessed and certified as meeting the requirements of

## Regulation (EU) 2016/425 Module C2

For the following activities

**Manufacture of CHERRY (logo) QRYW202005 particle filtering half mask.**

**(Note: All products marked CE0598 must have a valid EU type-examination certificate issued under Module B or a valid EC type-examination certificate issued under Article 10 of Directive 89/686/EEC.)**

This certificate is valid from 19 October 2020  
and remains valid subject to satisfactory surveillance audits.  
Issue 1. Certified since 19 October 2020

Authorised by

**SGS FIMKO OY, Notified Body 0598**

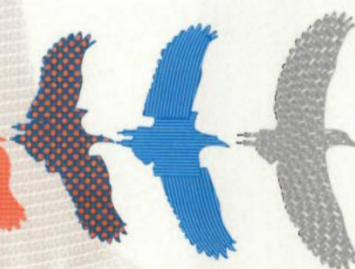
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中国认可  
国际互认  
检测  
TESTING  
CNAS L0599

**Test Report**      **SL52035261731301TX**      **Date: July 09, 2020**      **Page 1 of 6**  
 CHERRY MEDICAL HOLDING (SHENZHEN) CO., LTD.  
 ROOM 602, YUANLING BUILDING, NO.2002, HONGLI ROAD, NANTIAN COMMUNITY, YUANLING STREET,  
 FUTIAN DISTRICT, SHENZHEN, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A)Face mask

Style No. : QRYW202005

Sample Color : (A)WHITE

Previous No. : SL52025269209201TX

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Jun 29, 2020

Testing Period : Jun 29, 2020 - Jul 09, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Based on the results of the tests reported and the previous report SL52025269209201TX issued on Jun 20,2020, our Lab concluded that the recommendation level can be as below.

Sample No.	Recommendation Level
(A)	FFP2 NR

Signed for and on behalf of  
 SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)



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 Testing Center (Shanghai)    中国·上海·徐汇区宜山路889号3号楼 邮编: 200233    t (86-21) 61402666    f (86-21) 64958763    e [sgs.china@sgs.com](mailto:sgs.china@sgs.com)

Test Result

**Personal Protective Equipment - Respiratory Protective Devices- Filtering Half Masks to Protect against Particles- Requirements, Testing, Marking**

EN 149:2001+A1:2009

**Clause 7.4 Packaging**

(EN 149:2001+A1:2009 Clause 8.2)

Test Requirement	Results	Comment
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.	Comply	Pass

**Clause 7.7 Practical Performance**

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	No imperfections	Pass

**Clause 7.8 Finish of Parts**

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs	Pass



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**Clause 7.9.1 Total Inward Leakage**

(EN 149:2001+A1:2009, Clause 8.5)

Test Requirement	Results	Comment
<p>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 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</p> <p>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</p>	Detail refer to Appendix 1	Meet FFP1 Meet FFP2

**Appendix 1: Summarization of Test Data**

Inward Leakage Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Zhou	1	A.R.	6.16	4.92	7.06	6.42	5.81	6.07
Luo	2	A.R.	8.04	7.47	6.51	7.18	7.11	7.26
Lu	3	A.R.	4.79	7.03	5.20	6.35	7.41	6.16
Wang	4	A.R.	4.77	6.39	5.27	5.31	5.14	5.38
Bao	5	A.R.	6.47	7.86	6.72	7.82	7.25	7.22
Ding	6	T.C.	5.13	5.90	5.38	5.74	5.71	5.57
Li	7	T.C.	8.21	5.72	6.73	8.99	7.44	7.42
Chen	8	T.C.	5.79	6.60	5.92	4.26	5.61	5.64
Song	9	T.C.	6.76	7.40	6.35	5.56	5.84	6.38
Ye	10	T.C.	8.40	7.02	7.36	6.94	7.84	7.51

Facial Dimension(mm)

Subject	Face length	Face Width	Face Depth	Mouth Width
Chen	125	150	120	58
Lu	115	132	107	48
Zhou	115	135	106	52
Li	125	130	107	46
Luo	125	136	100	43
Zheng	128	140	112	55
Wang	120	147	103	48
Song	120	140	100	50
Bao	130	134	104	50
Ding	134	150	110	52
Liu	120	135	117	50
Ye	126	137	105	52



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**Clause 7.13 Head Harness**

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Comply	Pass
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.	Comply	

**Clause 7.14 Field of Vision**

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The field of vision is acceptable if determined so in practical performance tests.	Comply	Pass

**Clause 7.18 Demountable Parts**

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	Comply	Pass

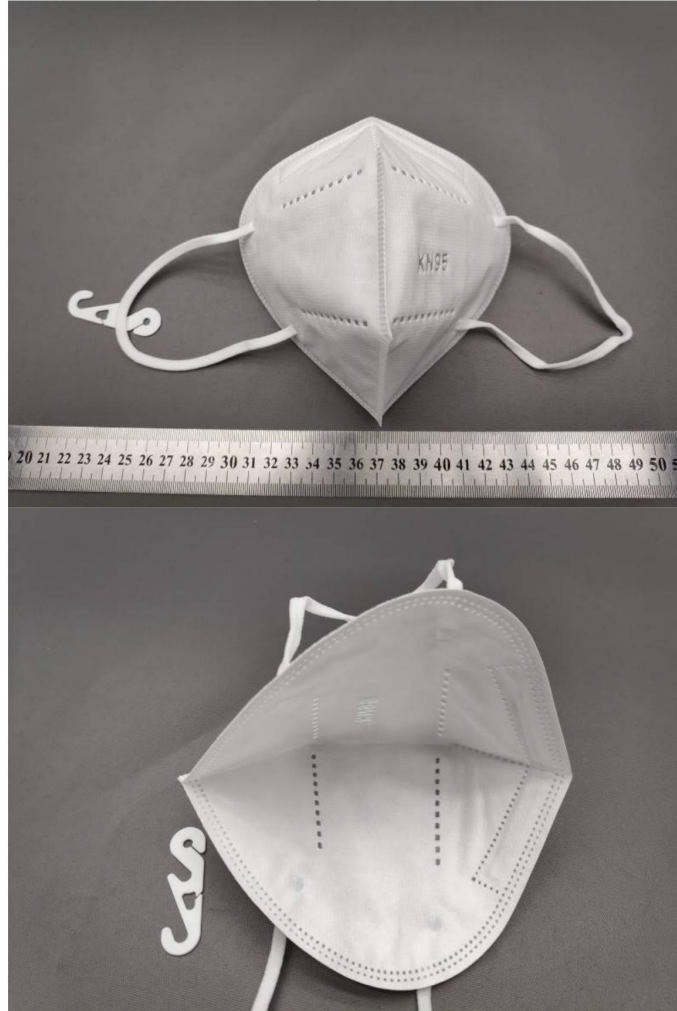
Test	Uncertainty
Total inward leakage	3.4%
Penetration of filter material	4.8%
Carbon dioxide content of the inhalation air	3.9%
Breathing resistance (30L/min)	5.9%
Breathing resistance (95L/min)	4.9%
Breathing resistance (160L/min)	4.3%



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Sample Photo



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Testing Center for Textiles

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