Prüfbericht-Nr.: *Test Report No.*:	**CN200T59 001**	**Auftrags-Nr.** *Order No.*:	**168292937**	Seite 1 von 13 *Page 1 of 13*
Kunden-Referenz-Nr.: *Client Reference No.*:	N/A	**Auftragsdatum:** *Order date*:	Nov. 30, 2020	
Auftraggeber: *Client*:	**Guangzhou Dayun Medical Technology Co.,Ltd.** No.632, Xintang Avenue, Xintang Town, Zengcheng District Guangzhou, Guandong, China			
Prüfgegenstand: *Test item*:	Disposable Medical Mask			
Bezeichnung / Typ-Nr.: *Identification / Type No.*:	DY-01			
Auftrags-Inhalt: *Order content*:	Type test			
Prüfgrundlage: *Test specification*:	EN 14683:2019+AC:2019 except for clause 5.2.6			

Wareneingangsdatum: *Date of sample receipt*:	Nov. 30, 2020	See Attachment: Photo documentation for details.
Prüfmuster-Nr.: *Test sample No.*:	20201013	
Prüfzeitraum: *Testing period*:	Nov. 30, 2020 to Dec. 24, 2020	
Ort der Prüfung: *Place of testing*:	See page 3	
Prüflaboratorium: *Testing laboratory*:	TÜV Rheinland (Shenzhen) Co., Ltd.	
Prüfergebnis*: *Test result**:	Pass	

geprüft von:
tested by: Yazhen Xu Yazhen Xu
Datum:
Date: Dec. 28, 2020
Stellung / *Position:* Engineer

kontrolliert von:
authorized by: Angela Chen Angela Ch
Ausstellungsdatum:
Issue date: Dec. 28, 2020
Stellung / *Position:* Department Manager

Sonstiges / *Other*:

- The test report consists of EN 14683 test report including this cover page (13 pages) and attachment: Photo documentation (3 pages).
- The Biocompatibility (clause 5.2.6) is not evaluated in this test report.

Zustand des Prüfgegenstandes bei Anlieferung: Prüfmuster vollständig und unbeschädigt
Condition of the test item at delivery: *Test item complete and undamaged*

* Legende:	1 = sehr gut	2 = gut	3 = befriedigend	4 = ausreichend	5 = mangelhaft
	P(ass) = entspricht o.g. Prüfgrundlage(n)		F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	N/A = nicht anwendbar	N/T = nicht getestet
Legend:	*1 = very good*	*2 = good*	*3 = satisfactory*	*4 = sufficient*	*5 = poor*
	P(ass) = passed a.m test specification(s)		*F(ail) = failed a.m test specification(s)*	*N/A = not applicable*	*N/T = not tested*

EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No. ..... :	**CN200T59 001**
Date of issue ..... :	**See cover page**
Total number of pages ..... :	**See cover page**
Testing Laboratory ..... :	**TÜV Rheinland (Shenzhen) Co., Ltd.**
Address ..... :	1601 R&D Room, 1602-1604, 17-18F, Building 7 Site C, Vanke Cloud City Phase I, XingKe First Street, Xili Street, Xili Community, Nanshan District, Shenzhen 518052, P.R. China
Applicant's name ..... :	**Guangzhou Dayun Medical Technology Co.,Ltd.**
Address ..... :	No.632, Xintang Avenue, Xintang Town, Zengcheng District Guangzhou, Guandong, China
Test specification:	
Standard ..... :	EN 14683:2019+AC:2019
Test procedure ..... :	Type test
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	EN 14683:2019+AC:2019_B
Test Report Form Originator ..... :	TÜV Rh (SZ)
Master TRF ..... :	2020-09
Test item description ..... :	Disposable Medical Mask
Trade Mark ..... :	KUNKKA
Manufacturer ..... :	Same as the applicant
Model/Type reference ..... :	DY-01
Classification ..... :	Type IIR

List of Attachments (including a total number of pages in each attachment):	
Attachment – Photo Documentation (3 pages)	
Summary of testing:	
Tests performed (name of test and test clause): Construction check according to: Clause 5.1.1 Materials and construction Clause 5.1.2 Design	**Testing location:** **TÜV Rheinland (Shenzhen) Co., Ltd.** 1601 R&D Room, 1602-1604, 17-18F, Building 7 Site C, Vanke Cloud City Phase I, XingKe First Street, Xili Street, Xili Community, Nanshan District, Shenzhen 518052, P.R. China
Clause 5.2.2 Bacterial filtration efficiency (BFE) Clause 5.2.3 Breathability Clause 5.2.4 Splash resistance Clause 5.2.5 Microbial cleanliness (Bioburden)	**TÜV Rheinland (Shanghai) Co., Ltd.** Shanghai TÜV Rheinland Building, No. 177 , Lane 777, West Guangzhong Road, Jing'an District, Shanghai, 200072, P.R.China

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Figure 1 Top view of packaging box

Figure 2 Front view of packaging box

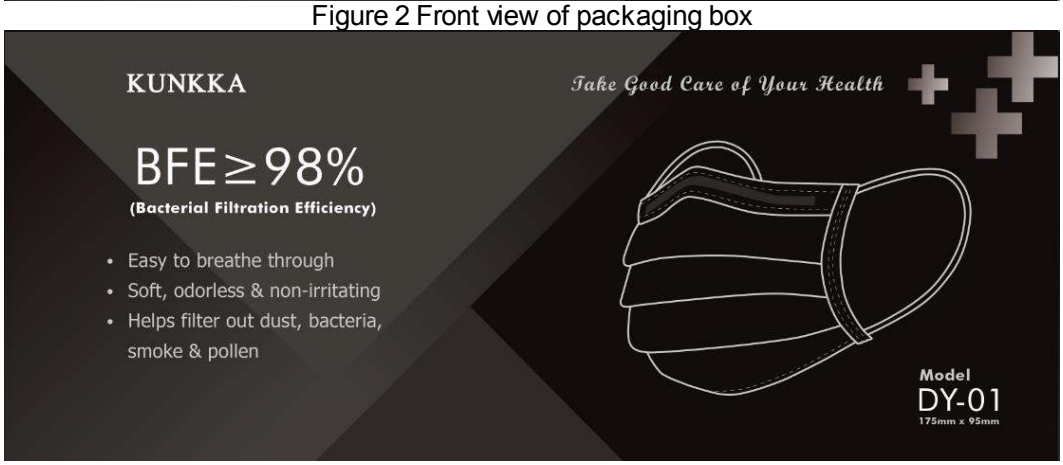

Figure 3 Back view of packaging box

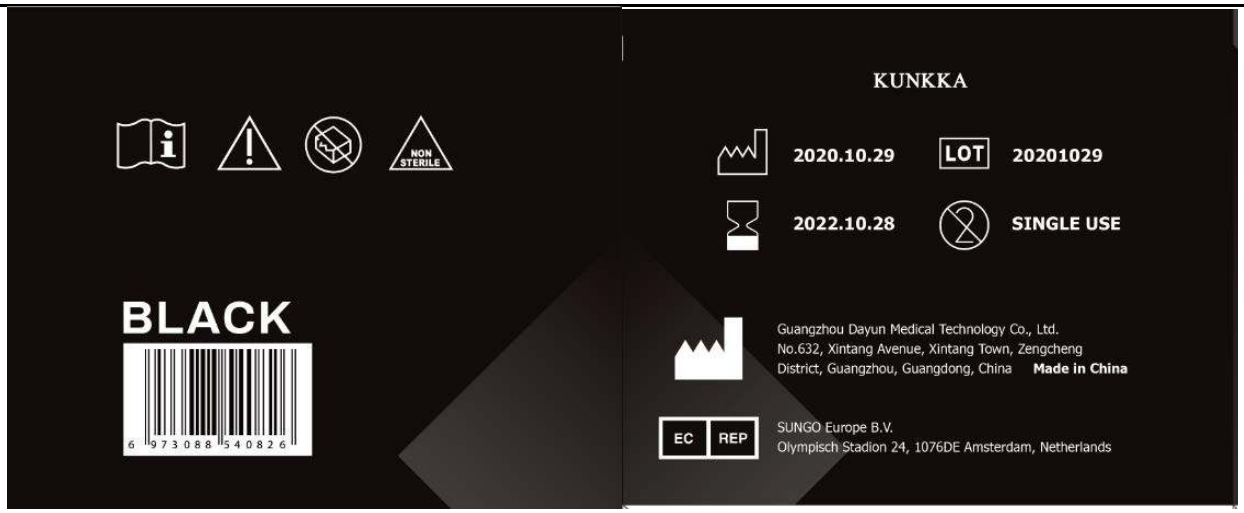

Figure 4 Side view of packaging box

INSTRUCTION FOR USE

Name: Disposable medical mask（Non-sterile）

Intend Use:

The Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material.
These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

Cautions:

1. Check the package completeness before using. Check the label, manufacturing date and validity time, to make sure the product is in valid date.
2. Do not use if the package damaged.
3. Do not reuse. Reusing may cause cross-contamination.

Instruction for use:

1. Place ear loops over ear.
2. Extend mask above nostrils and below chin.
3. Pinch nose piece to ensure snug fit.

Storage:

The product should be stored in a cool (Min 15℃) dry area, away from heat and direct sunlight.

Shelf life: 2 years

Symbols meaning:

Symbol	Introductions	Symbol	Introductions
MD	medical device	CE	CE Symbol
NON STERILE	non-sterile		Warnings and Precautions
	Do not reuse" are "single use, "Use only once	LOT	Batch Code
	Manufacture Date		Manufacturer Name Address
EC REP	Name and Address of European Union Representative		Use by
	Consult instructions for use		Keep dry

Manufacturer Information

Guangzhou Dayun Medical Technology Co., Ltd.
No.632, Xintang Avenue, Xintang Town, Zengcheng District, Guangzhou, Guangdong, China

EC REP SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Version: A/0
Issue date: April 20, 2020

Figure 5 Instruction for use

合格证 Q.C.PASSED	
产品名称 Product	一次性使用医用口罩（非灭菌） Disposable medical mask（Non-sterile）
限值标准 Limit Standard	EN14683:2019+AC:2019
品　　牌 Brand	KUNKKA
产品型号 Model	DY-01
产品颜色 Colour	黑色 Black
产品规格 Spec.	17.5*9.5cm
包装规格 Packing Spec.	50片/盒 50pcs/box
主要成分 Material	70% 无纺布 30% 熔喷布 70% PP non-woven, 30% melt-blown filter
生产批号 Lot No.	20201029
质 检 员 QC	QC01
检验日期 Inspection Date	2020年10月29日 29th of Oct 2020
生产日期 Production Date	2020年10月29日 29th of Oct 2020
有效期限 Expiry Date	2022年10月28日 28th of Oct 2022
生产单位 Manufacturer	广州达运医疗科技有限公司 Guangzhou Dayun Medical Technology Co., Ltd.
生产地址 Address	广州市增城区新塘镇新塘大道632号自编B2栋一楼南侧 Building B2, No.632, Xintang Avenue, Xintang Town, Zengcheng District, Guangzhou

广州达运医疗科技有限公司 检验合格章

Figure 6 Certificate

Testing

Date of receipt of test item(s).....: See cover page

Dates of tests performed.....: See cover page

Possible test case verdicts:

- test case does not apply to the test object ..... : N/A
- test object does meet the requirement..... : P (Pass)
- test object was not evaluated for the requirement ... : N/E (collateral standards only)
- test object does not meet the requirement..... : F (Fail)

General remarks:

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Name and address of factory (ies) .....: Same as the applicant

General product information:

1, The tested medical mask classified as type IIR.
2, The Biocompatibility (clause 5.2.6) is not evaluated in this test report.
3, The test results are for reference only. Relevant certification may be needed if the mask is intended to be sold in Europe.

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
4	**Classification**		**P**
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.	Type IIR	**P**
5	**Requirements**		**P**
5.1	**General**		**P**
5.1.1	**Materials and construction**		**P**
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	3 ply designed with two layers of nonwoven fabric and one layer of melt-blown nonwoven.	**P**
	The medical face mask shall not disintegrate, split or tear during intended use.		**P**
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.		**P**
5.1.2	**Design**		**P**
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.		**P**
	Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	With nose clip	**P**
5.2	**Performance requirements**		**P**
5.2.1	**General**		**P**
	All tests shall be carried out on finished products or samples cut from finished products.		**P**
5.2.2	**Bacterial filtration efficiency (BFE)**		**P**
	When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	See appended table 5.2.2	**P**
	For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE.	Not such mask.	**N/A**
	When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually.	Same characteristics and same layer-composition	**N/A**
	The lowest performing panel or area shall determine the BFE value of the complete mask	See above	**N/A**
5.2.3	**Breathability**		**P**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.	See appended table 5.2.3	**P**
	If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).		**N/A**
5.2.4	**Splash resistance**		**P**
	When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.	See appended table 5.2.4	**P**
5.2.5	**Microbial cleanliness (Bioburden)**		**P**
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ⩽ 30 CFU/g tested (see Table 1).	See appended table 5.2.5	**P**
5.2.6	**Biocompatibility**		**N/E**
	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact.	The biocompatibility is not evaluated in this test report.	**N/E**
	The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime.		**N/E**
	The results of testing should be documented according to the applicable parts of the EN ISO 10993 series.		**N/E**
	The test results shall be available upon request.		**N/E**
6	**Marking, labelling and packaging**		**P**
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied.	See “Copy of marking plate”.	**P**
	The following information shall be supplied:		**P**
	a) number of this European Standard;		**P**
	b) type of mask (as indicated in Table 1).		**P**
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		**P**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

5.2.2	TABLE: Bacterial filtration efficiency (BFE)							P
Batch/ lot no.:	**Test Specimen no.:**	**Dimension of the test specimen L x W (mm x mm)**	**test area (cm^2)**	**Flow rate (l/min)**	**Mean of the total plate counts of the two positive controls**	**Mean plate count of the negative controls**	**BFE for each test specimen (%)**	**Remarks**
20201013	1	100 x 100	50	28.3	2120	＜1	99.9	--
	2	100 x 100	50	28.3			99.9	--
	3	100 x 100	50	28.3			99.9	--
	4	100 x 100	50	28.3			99.9	--
	5	100 x 100	50	28.3			99.9	--

Supplementary information:
1, Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.
2, The side of the test specimen was facing towards the challenge aerosol: the inside of the test specimen.

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

5.2.3	TABLE: Breathability (Differential pressure)				P
Batch/ lot no.:	**Test Specimen number-Test area number**	**Differential pressure for each test area (Pa/cm²)**	**The averaged differential pressure for each test specimen (Pa/cm²)**	**Flow rate (l/min)**	**Remarks**
20201013	1-1	37.9	36.6	8.0	--
	1-2	37.5		8.0	--
	1-3	38.4		8.0	--
	1-4	31.9		8.0	--
	1-5	37.3		8.0	--
	2-1	37.8	36.4	8.0	--
	2-2	40.2		8.0	--
	2-3	34.7		8.0	--
	2-4	32.7		8.0	--
	2-5	36.8		8.0	--
	3-1	36.7	35.2	8.0	--
	3-2	34.8		8.0	--
	3-3	38.9		8.0	--
	3-4	33.1		8.0	--
	3-5	32.6		8.0	--
	4-1	35.3	34.6	8.0	--
	4-2	33.7		8.0	--
	4-3	38.1		8.0	--
	4-4	32.6		8.0	--
	4-5	33.6		8.0	--
	5-1	35.8	34.8	8.0	--
	5-2	32.0		8.0	--
	5-3	35.2		8.0	--
	5-4	34.8		8.0	--
	5-5	36.6		8.0	--

Supplementary information:

Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.

5.2.4	TABLE: Splash resistance	P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

Batch/ lot no.:	Test mask no.:	The material of tested mask	Test result (Pass/fail)	Remarks
20201013	**1**	**See clause 5.1.1**	**Pass**	--
	2		**Pass**	--
	3		**Pass**	--
	4		**Pass**	--
	5		**Pass**	--
	6		**Pass**	--
	7		**Pass**	--
	8		**Pass**	--
	9		**Pass**	--
	10		**Pass**	--
	11		**Pass**	--
	12		**Pass**	--
	13		**Pass**	--
	14		**Pass**	--
	15		**Pass**	--
	16		**Pass**	--
	17		**Pass**	--
	18		**Pass**	--
	19		**Pass**	--
	20		**Pass**	--
	21		**Pass**	--
	22		**Pass**	--
	23		**Pass**	--
	24		**Pass**	--
	25		**Pass**	--
	26		**Pass**	--
	27		**Pass**	--
	28		**Pass**	--
	29		**Pass**	--
	30		**Pass**	--
	31		**Pass**	--
	32		**Pass**	--

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

1, Splash resistance pressure ≥16.0 kPa.

2, Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.

3, The description of target area tested: the centre of outside.

4, Any technique used to enhance visual detection of synthetic blood: none.

5, The temperature and relative humidity for testing: 21 °C and 85 %.

6, Description of any pre-treatment techniques used: constant temperature and humidity machine was used.

5.2.5	TABLE: Microbial cleanliness (Bioburden)				P
Batch/ lot no.:	**Mask(under test) no.:**	**Weight of each mask (g)**	**Total bioburden per individual mask (CFU)**	**Total bioburden per gram (CFU/g)**	**Remarks**
20201013	**1**	**3.35**	**81**	**24.18**	**--**
	2	**3.35**	**75**	**22.39**	**--**
	3	**3.40**	**72**	**21.18**	**--**
	4	**3.36**	**63**	**18.75**	**--**
	5	**3.35**	**66**	**19.70**	**--**
Supplementary information:					

End of EN 14683 test report

Product: Disposable Medical Mask

Type Designation: DY-01

Figure 1 General view of mask

Figure 2 General view of mask

Product: Disposable Medical Mask

Type Designation: DY-01

Figure 3 General view of mask

Figure 4 General view of mask (3 ply)

Product: Disposable Medical Mask

Type Designation: DY-01

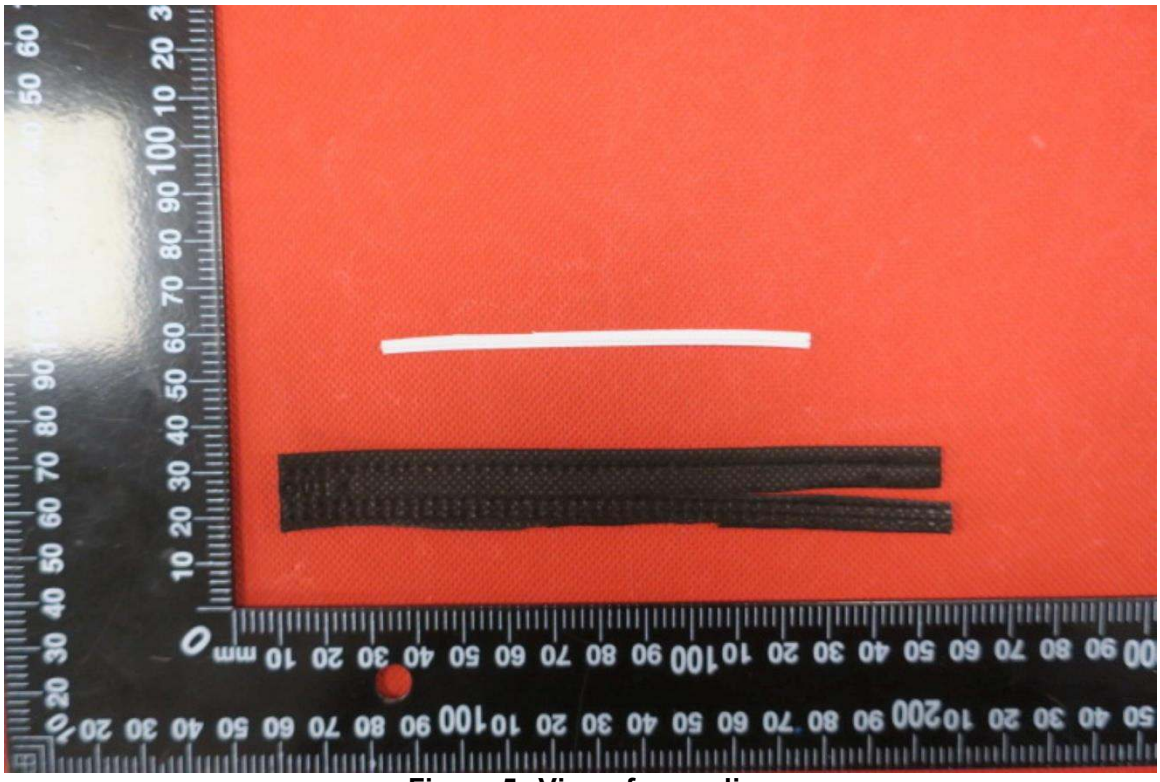

Figure 5 View of nose clip

END OF THE PHOTO DOCUMENTATION

TÜVRheinland®
Precisely Right.

Test Report No.: 244283190a 001

Client: **GUANGZHOU DAYUN MEDICAL TECHNOLOGY CO., LTD.**

Contact Information: No. 632, Xintang Avenue, Xintang Town, Zengcheng District, Guangzhou Guangdong, China
Contact Person： Liupan

Sample Description As Declared :

No. Of Sample	100pcs
Product Description	Disposable Medical Mask
Colour	Black
Model No.	DY-01
Product Type	Single shift use only
Claimed Classification	Type IIR

Sample obtaining method: Sending by customer

Condition at delivery: *Test item complete and undamaged.*

Sample Receiving date: 2020-12-01

Delivery condition: *Apparent good, Samples tested as received*

Test Period: 2020-12-01 to 2020-12-24

Place of testing: *Textiles laboratory Shanghai and Chemical laboratory*

Test Specification:
EN 14683:2019 + AC: 2019 Medical Face Masks- Requirements and Test Methods

Test Result
Please refer to next page

For and on behalf of

TÜV Rheinland (Shanghai) Co., Ltd.

2021-02-02	Joyce Zhou/Assistant Technical Manager	Peonia Zhang/ Senior Project Engineer
Date	*Name/Position*	*Name/Position*

Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed. This test report relates to the above mentioned test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products. "Decision Rule" document announced in our website (https://www.tuv.com/landingpage/en/qm-gcn/) describes the statement of conformity and its rule of enforcement for test results are applicable throughout this test report

Summary of test results

Clause	Test Description	M001
5.2.2	Bacterial filtration efficiency	M
5.2.3	Breathability	M
5.2.4	Splash resistance	M
5.2.5	Microbial cleanliness	M

Note : M = Meet Performance Standard F = Below Performance Standard
= No Specified Requirement * = No Submitted Information
N/A = Not Applicable

Material list

Material No.	Material	Color	Location
M001	Whole Product	Black	Disposable Medical Mask

1. Bacterial filtration efficiency

Test method	:	EN 14683:2019+AC：2019 Clause 5.2.2
Test Side:	:	Face side
Test specimen (L x M)	:	100mm x 100mm
Test area	:	50 cm^2
Flow rate	:	28.3 l/min
Mean of the total plate counts of the two positive controls	:	2120 CFU
Mean plate count of the negative controls	:	<1 CFU
Mean particle size	:	3.0±0.3μm
Test bacteria	:	*Staphylococcus aureus* ATCC 6538
Pre-conditioning	:	21±5°C and 85±5 % relative humidity for at least 4h
Requirement	:	Type IIR: ≥ 98%

M001

	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
B (%)	99.9	99.9	99.9	99.9	99.9
Conclusion	Pass				

2. Breathability

Test method	:	EN 14683:2019+AC：2019 Clause 5.2.3
Flow rate	:	8 l/min
Test area	:	4.9cm^2
Test location	:	Centre, Top-left, Top-right, Bottom-left, Bottom-right
Pre-conditioning	:	21±5°C and 85±5 % relative humidity for at least 4h
Requirement	:	Type IIR: <60Pa/cm^2

M001

Specimen	Pressure (Pa/cm^2)					
	Area 1	Area 2	Area 3	Area 4	Area 5	Mean
1	37.9	37.5	38.4	31.9	37.3	36.6
2	37.8	40.2	34.7	32.7	36.8	36.4
3	36.7	34.8	38.9	33.1	32.6	35.2
4	35.3	33.7	38.1	32.6	33.6	34.6
5	34.8	32.0	35.2	34.8	36.6	34.8
Conclusion	Pass					

3. Splash resistance

Test method : EN 14683:2019+AC：2019 Clause 5.2.4
Requirement : Type IIR: ≥16.0kPa no penetration

M001

Specimen	Observation	Specimen	Observation	Specimen	Observation	Specimen	Observation
1	N.P.	9	N.P.	17	N.P.	25	N.P.
2	N.P.	10	N.P.	18	N.P.	26	N.P.
3	N.P.	11	N.P.	19	N.P.	27	N.P.
4	N.P.	12	N.P.	20	N.P.	28	N.P.
5	N.P.	13	N.P.	21	N.P.	29	N.P.
6	N.P.	14	N.P.	22	N.P.	30	N.P.
7	N.P.	15	N.P.	23	N.P.	31	N.P.
8	N.P.	16	N.P.	24	N.P.	32	N.P.
Conclusion		Pass					

Remark: N.P. = no penetration P.F. = penetration was found

4. Microbial cleanliness (Bioburden)

Test method : EN 14683:2019+AC：2019 Clause 5.2.5
Requirement : Type IIR: ≤30 CFU/g

M001

	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
Weight of each mask (g)	3.35	3.35	3.40	3.36	3.35
Total bioburden per individual mask (CFU/mask)	81	75	72	63	66
Total bioburden per gram (CFU/g)	24.18	22.39	21.18	18.75	19.70
Conclusion	Pass				

Photo:

- END -

General Terms and Conditions of Business of TÜV Rheinland in Greater China

1. Scope

1.1 These General Terms and Conditions of Business of TÜV Rheinland in Greater China ("GTCB") is made between the client and one or more member entities of TÜV Rheinland in Greater China as applicable as the case may be ("TÜV Rheinland"). The Greater China hereof refers to Mainland China, Hong Kong and Taiwan.The client hereof includes:

(i) a natural person capable to form legally binding contracts under the applicable laws who concludes the contract not for the purpose of a daily use;

(ii) the incorporated or unincorporated entity duly organized, validly existing and capable to form legally binding contracts under the applicable law.

1.2 The following terms and conditions apply to agreed services including consultancy services, information, deliveries and similar services as well as ancillary services and other secondary obligations provided within the scope of contract performance.

1.3 Any standard terms and conditions of the client of any nature shall not apply and shall hereby be expressly excluded. No standard contractual terms and conditions of the client shall form part of the contract even if TÜV Rheinland does not explicitly object to them.

1.4 In the context of an ongoing business relationship with the client, this GTCB shall also apply to future contracts with the client without TÜV Rheinland having to refer to them separately in each individual case.

2. Quotations

Unless otherwise agreed, all quotations submitted by TÜV Rheinland can be changed by TÜV Rheinland without notice prior to its acceptance and confirmation by the other party.

3. Coming into effect and duration of contracts

3.1 The contract shall come into effect for the agreed terms upon the quotation letter of TÜV Rheinland or a separate contractual document being signed by both contracting parties, or upon the works requested by the client being carried out by TÜV Rheinland. If the client instructs TÜV Rheinland without receiving a quotation from TÜV Rheinland (quotation), TÜV Rheinland is, in its sole discretion, entitled to accept the order by giving written notice of such acceptance (including notice sent via electronic means) or by performing the requested services.

3.2 The contract term starts upon the coming into effect of the contract in accordance with article 3.1 and shall continue for the term agreed in the contract.

3.3 If the contract provides for an extension of the contract term, the contract term will be extended by the term provided for in the contract unless terminated in writing by either party with a six-week notice prior to the end of the contractual term.

4. Scope of services

4.1 The scope and type of the services to be provided by TÜV Rheinland shall be specified in the contractually agreed service scope of TÜV Rheinland by both parties. If no such separate service scope of TÜV Rheinland exists, then the written confirmation of order by TÜV Rheinland shall be decisive for the service to be provided.

4.2 The agreed services shall be performed in compliance with the regulations in force at the time the contract is entered into.

4.3 TÜV Rheinland is entitled to determine, in its sole discretion, the method and nature of the assessment unless otherwise agreed in writing or if mandatory provisions require a specific procedure to be followed.

4.4 On execution of the work there shall be no simultaneous assumption of any guarantee of the correctness (proper quality) and working order of either tested or examined parts nor of the installation as a whole and its upstream and/or downstream processes, organisations, use and application in accordance with regulations, nor of the systems on which the installation is based. In particular, TÜV Rheinland shall assume no responsibility for the construction, selection of materials and assembly of installations examined, nor for their use and application in accordance with regulations, unless these questions are expressly covered by the contract.

4.5 In the case of inspection work, TÜV Rheinland shall not be responsible for the accuracy or checking of the safety programmes or safety regulations on which the inspections are based, unless otherwise expressly agreed in writing.

4.6 If mandatory legal regulations and standards or official requirements for the agreed service scope change after conclusion of the contract, with a written notice to the client, TÜV Rheinland shall be entitled to additional remuneration for resulting additional expenses.

4.7 The services to be provided by TÜV Rheinland under the contract are agreed exclusively with the client. A contract of third parties with the services of TÜV Rheinland, as well as making available of and justifying confidence in the work results (test reports, test results, expert reports, etc.) is not part of the agreed services. This also applies if the client passes on work results - in full or in extracts - to third parties in accordance with clause 11.4.

5. Performance periods/dates

5.1 The contractually agreed periods/dates of performance are based on estimates of the work involved which are prepared in line with the details provided by the client. They shall only be binding if being confirmed as binding by TÜV Rheinland in writing.

5.2 If binding periods of performance have been agreed, these periods shall not commence until the client has submitted all required documents to TÜV Rheinland.

5.3 Articles 5.1 and 5.2 also apply, even without express approval by the client, to all extensions of agreed periods/dates of performance not caused by TÜV Rheinland.

5.4 TÜV Rheinland is not responsible for a delay in performance, in particular if the client has not fulfilled his duties to cooperate in accordance with clause 6.1 or has not done so in time and, in particular, has not provided TÜV Rheinland with all documents and information required for the performance of the service as specified in the contract.

5.5 If the performance of TÜV Rheinland is delayed due to unforeseeable circumstances such as force majeure, strikes, business disruptions, governmental regulations, transport obstacles, etc., TÜV Rheinland is entitled to postpone performance for a reasonable period of time which corresponds at least to the duration of the hindrance plus any time period which may be required to resume performance.

6. The client's obligation to cooperate

6.1 The client shall guarantee that all cooperation required on its part, its agents or third parties will be provided in good time and at no cost to TÜV Rheinland.

6.2 Design documents, supplies, auxiliary staff, etc. necessary for performance of the services shall be made available free of charge by the client. Moreover, collaborative action of the client must be undertaken in accordance with legal provisions, standards, safety regulations and accident prevention instructions. And the client represents and warrants that:

a) it has required statutory qualifications;

b) the product, service or management system to be certified complies with applicable laws and regulations; and

c) it doesn't have any illegal and dishonest behaviours or is not included in the list of Enterprises with Serious Illegal and Dishonest Acts of People's Republic of China.

If the client breaches the aforesaid representations and warranties, TÜV Rheinland is entitled to i) immediately terminate the contract/order without prior notice; and ii) withdraw the issued testing report/certificates if any.

6.3 The client shall bear any additional cost incurred on account of work having to be redone or being delayed as a result of late, incorrect or incomplete information provided by or lack of proper cooperation from the client. Even where a fixed or maximum price is agreed, TÜV Rheinland shall be entitled to charge extra fees for such additional expense.

7. Prices

7.1 If the scope of performance is not laid down in writing when the order is placed, invoicing shall be based on costs actually incurred. If no price is agreed in writing, invoicing shall be made in accordance with the price list of TÜV Rheinland valid at the time of performance.

7.2 Unless otherwise agreed, work shall be invoiced according to the progress of the work.

7.3 If the execution of an order extends over more than one month and the value of the contract or the agreed fixed price exceeds €2,500.00 or equivalent value in local currency, TÜV Rheinland may demand payments on account or in instalments.

8. Payment terms

8.1 All invoice amounts shall be due for payment without deduction on receipt of the invoice. No discounts and rebates shall be granted.

8.2 Payments shall be made to the bank account of TÜV Rheinland as indicated on the invoice, stating the invoice and client numbers.

8.3 In cases of default of payment, TÜV Rheinland shall be entitled to claim default interest at the applicable short term loan interest rate publicly announced by a reputable commercial bank in the country where TÜV Rheinland is located. At the same time, TÜV Rheinland reserves the right to claim further damages.

8.4 Should the client default in payment of the invoice despite being granted a reasonable grace period, TÜV Rheinland shall be entitled to cancel the contract, withdraw the certificate, claim damages for non-performance and refuse to continue performance of the contract.

8.5 The provisions set forth in article 8.4 shall also apply in cases involving returned cheques, cessation of payment, commencement of insolvency proceedings against the client's assets or cases in which the commencement of insolvency proceedings has been dismissed due to lack of assets.

8.6 Objections to the invoices of TÜV Rheinland shall be submitted in writing within two weeks of receipt of the invoice.

8.7 TÜV Rheinland shall be entitled to demand appropriate advance payments.

8.8 TÜV Rheinland shall be entitled to raise its fees at the beginning of a month if overheads and/or purchase costs have increased. In this case, TÜV Rheinland shall notify the client in writing of the rise in fees. This notification shall be issued one month prior to the date on which the rise in fees shall come into effect (period of notice of changes in fees). If the rise in fees remains under 5% per contractual year, the client shall not have the right to terminate the contract. If the rise in fees exceeds 5% per contractual year, the client shall be entitled to terminate the contract by the end of the period of notice of changes in fees. If the contract is not terminated, the changed fees shall be deemed to have been agreed upon by the time of the expiry of the notice period.

8.9 Only legally established and undisputed claims may be offset against claims by TÜV Rheinland.

9. Acceptance of work

9.1 Any part of the work result ordered which is complete in itself may be presented by TÜV Rheinland for acceptance as an instalment. The client shall be obliged to accept it immediately.

9.2 If acceptance is required or contractually agreed in an individual case, this shall be deemed to have taken place two (2) weeks after completion and handover of the work, unless the client refuses acceptance within this period stating at least one fundmental breach of contract by TÜV Rheinland.

9.3 The client is not entitled to refuse acceptance due to insignificant breach of contract by TÜV Rheinland.

9.4 If acceptance is excluded according to the nature of the work performance of TÜV Rheinland, the completion of the work shall take its place.

9.5 If the client was unable to make use of the time windows provided for within the scope of a certification procedure for auditing/performance by TÜV Rheinland and the certificate is therefore to be withdrawn (e.g. performance of surveillance audits), TÜV Rheinland is entitled to immediately charge a lump-sum compensation of 10% of the order amount as compensation for expenses. The client reserves the right to prove that the TÜV Rheinland has incurred no damage whatsoever or only a considerably lower damage than the above lump sum.

9.6 Insofar as the client has undertaken in the contract to accept services, TÜV Rheinland shall also be entitled to charge lump-sum damages in the amount of 10% of the order amount as compensation for expenses if the service is not called within one year after the order has been placed. The client reserves the right to prove that the TÜV Rheinland has incurred no damage whatsoever or only a considerably lower damage than the above mentioned lump sum.

10. Confidentiality

10.1 For the purpose of these terms and conditions, "confidential information" means all information, documents, images, drawings, know-how, data, samples and project documentation which one party (the "disclosing party") hands over, transfers or otherwise discloses to the other party (the "receiving party"), and the confidential information created during performance of work by TÜV Rheinland, including product testing data, defects, conformity to the technical standard and related reports. Confidential information also includes paper copies and electronic copies of such information. Confidential information is expressly not the data and know-how collected, compiled or otherwise obtained by TÜV Rheinland (non-personal) within the scope of the provision of services by TÜV Rheinland. TÜV Rheinland is entitled to store, use, further develop and pass on the data obtained in connection with the provision of services for the purposes of developing new services, improving services and analysing the provision of services.

10.2 The disclosing party shall mark all confidential information disclosed in written form as confidential before passing it onto the receiving party. The same applies to confidential information transmitted by e-mail. If confidential information is disclosed orally, the receiving party shall be appropriately informed in advance and the disclosing party shall confirm in writing the confidentiality nature of the information within five working days of oral disclosure. Where the disclosing party fails to do so within the stipulated period, the receiving party shall not take any confidentiality obligations hereunder towards such information.

10.3 All confidential information which the disclosing party transmits or otherwise discloses to the receiving party and which is created during performance of work by TÜV Rheinland:

a) may only be used by the receiving party for the purposes of performing the contract, unless expressly otherwise agreed in writing by the disclosing party;

b) may not be copied, distributed, published or otherwise disclosed by the receiving party, unless this is necessary for fulfilling the purpose of the contract or TÜV Rheinland is required to pass on confidential information, inspection reports or documentation to the government authorities, judicial court, accreditation bodies or third parties that are involved in the performance of the contract;

c) must be treated by the receiving party with the same level of confidentiality as the receiving party uses to protect its own confidential information, but never with a lesser level of confidentiality than that which is reasonably required.

10.4 The receiving party may disclose any confidential information received from the disclosing party only to those of its employees who need this information to perform the services required for the contract. The receiving party undertakes to oblige these employees to observe the same level of secrecy as set forth in this confidentiality clause.

10.5 Information for which the receiving party can furnish proof that:

a) it was generally known at the time of disclosure or has become general knowledge without violation of this confidentiality clause by the receiving party; or

b) it was disclosed to the receiving party by a third party entitled to disclose this information; or

c) the receiving party already possessed this information prior to disclosure by the disclosing party; or

d) the receiving party developed it itself, irrespective of disclosure by the disclosing party, shall not be deemed to constitute "confidential information" as defined in this confidentiality clause.

10.6 All confidential information shall remain the property of the disclosing party. The receiving party hereby agrees to immediately (i) return all confidential information, including all copies, to the disclosing party, and/or (ii) on request by the disclosing party, to destroy all confidential information, including all copies, and confirm the destruction of this confidential information to the disclosing party in writing, at any time if so requested by the disclosing party but at the latest and without special request after termination or expiry of the contract. This does not extend to include reports and certificates prepared for the client solely for the purpose of fulfilling the obligations under the contract, which shall remain with the client. However, TÜV Rheinland is entitled to make file copies of such reports, certificates and confidential information that forms the basis for preparing these reports and certificates in order to evidence the correctness of its results and for general documentation purposes required by laws, regulations and the requirements of working procedures of TÜV Rheinland.

10.7 From the start of the contract and for a period of three years after termination or expiry of the contract, the receiving party shall maintain strict secrecy of all confidential information and shall not disclose this information to any third parties or use it for itself.

11. Copyrights and rights of use, publications

11.1 TÜV Rheinland shall retain all exclusive copyrights in the reports, expert reports/opinions, test reports/results, results, calculations, presentations etc. prepared by TÜV Rheinland, unless otherwise agreed by the parties in a separate agreement. As the owner of the copyrights, TÜV Rheinland is free to grant others the right to use the work results for individual or all types of use ("right of use")

11.2 The client receives a simple, unlimited, non-transferable, non-sublicensable right of use to the contents of the work results produced within the scope of the contract, unless otherwise agreed by the parties in a separate agreement.The client may only use such reports, expert reports/opinions, test reports/results, results calculations, presentations etc. prepared within the scope of the contract for the contractually agreed purpose.

11.3 The transfer of right of use of the generated work results regulated in clause 11.2. of the GTCB is subject to full payment of the remuneration agreed in favour of TÜV Rheinland.

11.4 The client may use work results only complete and unshortened. The client may only pass on the work results in full unless TÜV Rheinland has given its prior written consent to the partial passing on of work results.

11.5 Any publication or duplication of the work results for advertising purposes or any further use of the work results beyond the scope regulaed in clause 11.2 needs the prior written approval of TÜV Rheinland in each individual case.

11.6 TÜV Rheinland may revoke a once given approval according to clause 11.5 at any time without stating reasons. In this case, the client is obliged to stop the transfer of the work results immediately at his own expense and, as far as possible, to withdraw publications.

11.7 The consent of TÜV Rheinland to publication or duplication of the work results does not entitle the client to use the corporate logo, corporate design or test/certification mark of TÜV Rheinland.

12. Liability of TÜV Rheinland

12.1 Irrespective of the legal basis, to the fullest extent permitted by applicable law, in the event of a breach of contractual obligations or tort, the liability of TÜV Rheinland for all damages, losses and reimbursement of expenses caused by TÜV Rheinland, its legal representatives and/or employees shall be limited to: (i) in the case of a contract with a fixed overall fee, three times the overall fee for the entire contract; (ii) in the case of a contract for annually recurring services, the agreed annual fee; (iii) in the case of a contract expressly charged on a time and material basis, a maximum of 20,000 Euro or equivalent amount in local currency; and (iv) in the case of a framework agreement that provides for the possibility of placing individual orders, three times of the fee for the individual order under which the damages or losses have occurred. Notwithstanding the above, in the event that the total and accumulated liability calculated according to the foregoing provisions exceeds 2.5 Million Euro or equivalent amount in local currency, the total and accumulated liability of TÜV Rheinland shall be only limited to and shall not exceed the said 2.5 Million Euro or equivalent amount in local currency.

12.2 The limitation of liability according to article 12.1 above shall not apply to damages and/or losses caused by malice, intent or gross negligence on the part of TÜV Rheinland or its vicarious agents. Such limitation shall not apply to damages for a person's death, physical injury or illness.

12.3 In cases involving a fundamental breach of contract, TÜV Rheinland will be liable even where minor negligence is involved. For this purpose, a "fundamental breach" is breach of a material contractual obligation, the performance of which permits the due performance of the contract. Any claim for damages for a fundamental breach of contract shall be limited to the amount of damages reasonably foreseen as a possible consequence of such breach of contract at the time of the breach (reasonably foreseeable damages), unless any of the circumstances described in article 12.2 applies.

12.4 TÜV Rheinland shall not be liable for the acts of the personnel made available by the client to support TÜV Rheinland in the performance of its services under the contract, unless such personnel made available is regarded as vicarious agent of TÜV Rheinland. If TÜV Rheinland is not liable for the acts of the personnel made available by the client under the foregoing provision, the client shall indemnify TÜV Rheinland against any claims made by third parties arising from or in connection with such personnel's acts.

12.5 Unless otherwise contractually agreed in writing, TÜV Rheinland shall only be liable under the contract to the client.

12.6 The limitation periods for claims for damages shall be based on statutory provisions.

12.7 None of the provisions of this article 12 changes the burden of proof to the disadvantage of the client.

13. Export control

13.1 When passing on the services provided by TÜV Rheinland or parts thereof to third parties in Greater China or other regions, the client must comply with the respectively applicable regulations of national and international export control law.

13.2 The performance of a contract with the client is subject to the proviso that there are no obstacles to performance due to national or international foreign trade legislations or embargos and/or sanctions. In the event of a violation, TÜV Rheinland shall be entitled to terminate the contract with immediate effect and the client shall compensate for the losses incured thereof by TÜV Rheinland.

14. Data protection notice

TÜV Rheinland processes personal data of the client for the purpose of fulfilling this contract. In addition, TÜV Rheinland also processes the data for other legal purposes in accordance with the relevant legal basis. The personal data of the client will only be disclosed to other natural or legal persons if the legal requirements are met. This also applies to transfers to third countries. The personal data will be deleted immediately as soon as a corresponding reason for deletion arises. Data subjects may exercise the following rights: right of information, right of rectification, right of deletion, right of processing limitation, right of objection, right of data transferability. In addition, persons concerned by the data processing have the right to revoke their consent at any time with effect for the future, as well as the right to file a complaint with the competent data protection supervisory authority. For further details on the processing of personal data by TÜV Rheinland as the person responsible or contract processor, please refer to the respective data protection information. You can contact the Group Data Protection Officer of TÜV Rheinland by e-mail at datenschutz@de.tuv.com or by post at the following address: TÜV Rheinland AG, c/o Group Data Protection Officer, Am Grauen Stein, 51105 Cologne, Germany.

15. Test material: transport risk and storage

15.1 The risk and costs for freight and transport of documents or test material to and from TÜV Rheinland as well as the costs of necessary disposal measures shall be borne by the client.

15.2 Any destroyed and otherwise worthless test material will be disposed of by TÜV Rheinland for the client at the expense of the client, unless otherwise agreed.

15.3 Undamaged test material shall be stored by TÜV Rheinland for four (4) weeks after completion of the test. If a longer storage period is desired, TÜV Rheinland charges an appropriate storage fee.

15.4 After the expiry of the 4 weeks or any longer period agreed upon, the test material will be disposed of by TÜV Rheinland for the client for a fee in accordance with clause 15.2.

16. Termination of the contract

16.1 Notwithstanding clause 3.3 of the GTCB, TÜV Rheinland and the client are entitled to terminate the contract in its entirety or, in the case of services combined in one contract, each of the combined parts of the contract individualy and independently of the continuation of the remaining services with six (6) months' notice to the end of the contractually agreed term.

16.2 For good causes, TÜV Rheinland may consider giving a written notice to the client to terminate the contract which includes but not limited to the following:

a) the client does not immediately notify TÜV Rheinland of changes in the conditions within the company which are relevant for certification or signs of such changes;

b) the client misuses the certificate or certification mark or uses it in violation of the contract;

c) in the event of several consecutive delays in payment (at least three times);

d) a substantial deterioration of the financial circumstances of the client occurs and as a result the payment claims of TÜV Rheinland under the contract are considerably endangered and TÜV Rheinland cannot reasonably be expected to continue the contractual relationship.

16.3 In the event of termination with written notice by TÜV Rheinland for good cause, TÜV Rheinland shall be entitled to a lump-sum claim for damages against the client if the conditions of a claim for damages exist. In this case, the client shall owe 15% of the remuneration to be paid until the end of the fixed contract term as lump-sum compensation. The client reserves the right to prove that there is no damage or a considerably lower damage, TÜV Rheinland reserves the right to prove a considerably higher damage in individual cases.

16.4 TÜV Rheinland is also entitled to terminate the contract with written notice if the client has not been able to make use of the time windows for auditing /service provision provided by TÜV Rheinland within the scope of a certification procedure and the certificate therefore has to be withdrawn (for example during the performance of monitoring audits). Clause 16.3 applies accordingly.

17. Partial invalidity, written form, place of jurisdiction and dispute resolution

17.1 All amendments and supplements must be in writing in order to be effective. This also applies to amendments and supplements to this clause 17.1.

17.2 Should one or several of the provisions under the contract and/or these terms and conditions be or become ineffective, the contracting parties shall replace the invalid provision with a legally valid provision that comes closest to the content of the invalid provision in legal and commercial terms.

17.3 Unless otherwise stipulated in the contract, the governing law of the contract and these terms and conditions shall be chosen following the rules as below:

a) if TÜV Rheinland in question is legally registered and existing in the People's Republic of China, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of the People's Republic of China.

b) if TÜV Rheinland in question is legally registered and existing in Taiwan, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of Taiwan.

c) if TÜV Rheinland in question is legally registered and existing in Hong Kong, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of Hong Kong.

17.4 Any dispute in connection with the contract and these terms and conditions or the execution thereof shall be settled friendly through negotiations. Unless otherwise stipulated in the contract, if no settlement or no agreement in respect of the extension of the negotiation period can be reached within two months of the arising of the dispute, the dispute shall be submitted:

a) in the case of TÜV Rheinland in question being legally registered and existing in the People's Republic of China, to China International Economic and Trade Arbitration Commission (CIETAC) to be settled by arbitration under the Arbitration Rules of CIETAC in force when the arbitration is submitted. The arbitration shall take place in Beijing, Shanghai, Shenzhen or Chongqing as appropriately chosen by the claiming party.

b) in the case of TÜV Rheinland in question being legally registered and existing in Taiwan, to Chinese Arbitration Association Taipei Branch to be arbitrated in accordance with its then current Rules of Arbitration. The arbitration shall take place in Taipei.

c) in the case of TÜV Rheinland being legally registered and existing in Hong Kong, to Hong Kong International Arbitration Centre (HKIAC) to be settled by arbitration under the HKIAC Administered Arbitration Rules in force when the Notice of Arbitration is submitted in accordance with these rules. The arbitration shall take place in Hong Kong.

The decision of the relevant arbitration tribunal shall be final and binding on both parties. The arbitration fee shall be borne by the losing party.

May 2019

TÜV Rheinland (Shanghai) Co., Ltd., Shanghai TüV Rheinland Building, No. 177 , Lane 777, West Guangzhong Road, Jing'an District,
Shanghai, 200072, P.R.China
Tel +86 21 6108 1188 Fax +86 21 6108 1099 Mail: service-gc@tuv.com Web: www.tuv.com

File No: CE-TCF-001 A/0

EC Declaration of Conformity

Applicant

Name: Guangzhou Dayun Medical Technology Co.,Ltd.
Address: No.632, Xintang Avenue, Xintang Town, Zengcheng District Guangzhou, Guangdong, China

EC-Representative

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Disposable medical mask（Non-sterile）

Model: DY-01(17.5cm×9.5cm), DY-02(14.5cm×9.5cm), DY-03(12.0cm×7.0cm)

Classification: Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)
Conformity Assessment Route: Annex VII

We confirm our product can meet the requirement of Medical Device Directive(MDD 93/42/EEC) and the following harmonized standards.

EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2008+A1:2013
ISO 10993-1:2018
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN 14683:2019

Signature:
(Name/ Position)

Date: 2020年5月15日

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

Ref. No.: MDD2020MA1224

MDD/IVDD EC REP Agreement

Party A甲方:Guangzhou Dayun Medical Technology Co.,Ltd.

Add地址: No.632,Xintang Avenue,Xintang Town,Zengcheng Distrit Guangzhou,Guangdong,China
Contact联系人: Zhang Xiaoqin

Tel电话: +86 (020)82453846

Fax传真: +86 (020)82453846

Email邮箱: 980628779@qq.com

Party B乙方: *SUNGO Europe B.V.*

VAT：NL857821659B01

Add地址: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Contact联系人: SUNGO Secretary

Tel电话/Fax传真: +31（0）2021 11106

E-mail邮箱: ec.rep@sungogroup.com

Party A hereby appoints Party B as the EC authorized Representative for their Medical Device with CE mark and Party B accepts the appointment to be the EC authorized Representative for Party A in the market of European Union (E.U.). Both parties enter this agreement as follow:
甲方任命乙方为CE医疗产品欧盟授权代表，乙方接受甲方任命,为甲方在欧盟市场的CE医疗产品授权代表。双方签署下列协议：

1. Party A 甲方

1.1 Party A assures to provide the updated technical files of each product category with CE mark to Party B (Product categories relevant information please see the appendix A). Party A could firstly provide Part A of the technical file, and Part B would be submitted if required. If Party A can not provide the required technical file to Party B within 30 days after approval of CE certification or before using CE mark for "self declaration" products, this agreement will be terminated automatically, Party A should take on any aftereffect by itself. The technical files should be the electronic copy (PDF/WORD/JPG/TXT version), the written copy would be submitted if required by the competent authority. Detail of the requirements of the submitted files in appendix B.
甲方确保在认证结束后向乙方提供每一大类带CE标志产品的、最新的技术文档（甲方申请CE认证的产品信息见附录一）。甲方可以先提供CE技术文档的PART A部分，PART B内容只有在需要时才提交。如果甲方在认证结束取得证书之后的30天内，或者"自我声明"产品在使用CE标记之前，仍然没有提供给乙方符合要求的CE技术文档的，本协议自动失效，甲方承担由此而引起的所有后果。甲方必需提交电子文档文件，文件可以PDF/WORD/JPG/TXT格式的任何一种提交。书面文件只有在欧盟当局需要审核时才提交乙方，所提交文档内容的要求，详见本协议"附件二"。

1.2 Party A shall keep the Party B informed of any changes or updates of the mentioned information in attachment 1 at all times.

如果附件1中的文件有任何变化或更新，甲方应及时通知乙方。

1.3 If any accident/near accident of products, including any serious adverse event during clinical investigation in premarket stage, happens within boundary of E.U., Party A shall help Party B to investigate the reason in time, and complete & submit the initial INCIDENT report together with Party B by using the standard "Manufacturer's Incident Report", to the competent Authority within the timeframe required by the Section 5.1.7 of Guideline's on a Medical Devices Vigilance System(MEDDEV 2.12-1 rev8, Jan, 2013), listed as follows:
如果产品在欧盟境内发生事故或者准事故（包括在上市前的临床调查阶段发生的严重不良事故），甲方应及时配合乙方调查原因，并同乙方一起在下列医疗器械警戒系统指南（MEDDEV 2.12-1 rev8, Jan, 2013）Section 5.1.7 中规定的期限内完成和提交初始报告。
Serious public health threat: IMMEDIATELY (without any delay that could not be justified) but not later than 2 calendar days after awareness by Party A of this threat.
严重威胁公共卫生安全：立即报告（不允许任何无正当理由的延误），报告时限是不应迟于甲方发现该威胁后2个自然日。
Death or UNANTICIPATED serious deterioration in state of health: IMMEDIATELY (without any delay that could not be justified) after party A established a link between the device and the event but not later than 10 elapsed calendar days following the date of awareness.
死亡或意外的健康状况严重恶化：立即报告（不允许任何无正当理由延误），报告时限是甲方在确认医疗器械和事故关联后，但是不应迟于从发现该事件之日起10个自然日。
Others: IMMEDIATELY (without any delay that could not be justified) after Party A established a link between the device and the event but not later than 30 elapsed calendar days following the date of awareness of the event.
其他：立即报告（不允许任何无正当理由的延误），报告时限是甲方在确认医疗器械和事故关联后，但是不应迟于从发现该事件之日起30个自然日。

Party A shall present the investigation result and final report to Party B according to MDD 93/42/EEC (MDD products) ,IVDD 98/79/EC (IVDD products) and the Guidance of vigilance system. If the accident of the product happens out of E.U., Party A shall notify Party B as soon as possible, and Part B should make decision whether to report to competent authority or not.
甲方应在《欧洲共同体理事会法令》按MDD 93/42/EEC（MDD产品）或IVDD 98/79/EC（IVDD产品）和《警戒系统指南》规定的时间内向乙方报告调查结果和最终报告。如带CE标志的产品，其事故、准事故发生在欧盟境外，甲方应尽快告知乙方，并由乙方决定是否向主管当局报告。

If the above mentioned accident/near accident of products was known by Party A at first, Party A must notify Party B in one working day and provide the complete report of the investigation, analysis and disposal result of the accident/near accident to Party B by E-mail or other effective means as soon as possible.
如果上述事故、准事故是通过甲方渠道先期获得的，甲方须立即在一个工作日内转告乙方；然后，对事故、准事故的调查、分析和处理结果的报告，用电子邮件或其他有效的方式尽快通知乙方。

1.4 Party A should keep the complete sales list of all of the products exporting to any area of E.U. by electrical documents in English at least 5 years after the last batch product's manufacturing, in order to be provided by Party B for the using to be transferred or inspected to the relevant competent authorities of E.U., Party A shall assure the accuracy and the validity of the data.
甲方出口欧盟地区的所有产品的销售清单（包括OEM的销售清单），在产品停产后至少五年期间，必须用英文文字、电子文档形式保留完整无缺，以备乙方随时用于欧盟官方的调用、检查。甲方应确保其提供的数据的准确性和真实性。

1.5 Party A must notice Party B the complaint record and the result of disposal on the accident of products immediately, and Party A should save, transfer, check-up any of the record according to the clause 1.4.
甲方针对客户/用户的事故或者准事故的投诉、抱怨记录和处理结果，除了应该及时通知乙方以外，所有记录的保存、调用、检查，按照1.4条款办理。

1.6 Party A should appoint one or two persons as the primacy linkman who connect with Party B

and deal with the normal daily grind according to this agreement. Information of both Parties' linkman should be written in appendix C.
甲方需指定一至二人，作为甲、乙双方的第一联络人，主要职责是与乙方共同协调、处理本协议条款规定范围内的日常工作。双方联络人的联络方式记录在本协议的附件（三）。

1.7 Party A shall fully realize the risk of selling its products to EU market without product registration to relevant competent authority of E.C. If it caused by Party A, such as delay, omittance or conceal of files submission, Party A should take the aftereffects such as warning, penalty or even the results that the CE certificate will be withdrawn, and the distribution of its products in EU market will be prohibited.
甲方应充分认识到本企业产品由于迟缓、延误、疏漏或者隐瞒而造成产品没有登记备案就销售欧盟市场带来的风险。如果由于甲方的原因，发生产品没有登记备案就进入欧盟市场的，甲方将承担罚款、警告，甚至直至吊销CE产品证书和禁止产品进入欧盟市场的后果。

1.8 Part A shall notify of the intention to Part B to carry out a clinical investigation for MDD or AIMDD, or the intention to carry out a performance evaluation for IVDD performed in EU.
甲方应通知乙方在欧盟其对医疗器械或者有源植入性医疗器械进行临床试验的计划，或对体外诊断试剂进行性能评估的计划。

2. Party B 乙方

2.1 About the register for Party A's products with CE mark to relevant competent authority of E.C. (Details are in appendix D), Party A shall apply it in written to Party B and supply all the files and forms needed. Party B shall review it within 7 working days, and submit to competent authority of the country in which Party B is located (Netherlands) within 5 days. If Party A's application is returned/rejected by Party B or the competent authority for the contents of the submitted files, the above schedule will be adjusted accordingly. The details of the application shall be in the attachments of this agreement. (The charges of products register in EU shall be paid accordingly by Party A and a contract may be signed separately if necessary.)
甲方已取得CE证书的产品按欧盟相关规定（详见协议附件四），必须需要办理CE产品欧盟登记备案的，需先由甲方提出申请，并提供所有符合规定的文件并填写申请表格，经乙方初步认可后，由乙方负责在7个工作日完成初审，5个工作日内提交乙方所在国荷兰主管当局审核申请登记备案的文件。但是由于甲方提交文件内容方面的原因被乙方或者当局退回/拒绝的申请，不在此时间规定之列。提交文件的内容、时间等细节，应该在双方协议的附件中明示。（登记备案的费用甲乙方根据实际注册情况另外商议并签订合同）

If it needs any expenditure by the competent authority, only after getting Party A's approval, then Party A can take on the payment. If Party A's products register fails by Party B's reason, according to EU relevant laws Party B will be given a warning, penalty and even the qualification of the European Representative will be revoked.
如果需要任何主管机构审核上述登记备案如需要收取相关费用的，需经甲方同意方可由乙方代为支付。如果由于是乙方的原因，甲方的申请登记备案手续失败而影响企业产品正常进入欧盟市场的，根据欧盟有关法律法规，乙方将受到警告、罚款、吊销担任欧盟代表资格的处罚。

2.2 Party B shall reserve technical files of each category of Party A's products with CE mark, and take up the responsibility of keeping, confidentiality and submission. The technical files shall be reserved at least 5 years after the last batch product's manufacturing. Once competent authority needs the technical files (including new edition technical files which had already registered) of each category of Part A's products with CE mark. Party B should send them to competent authority within ten working days.
乙方应保留甲方每一大类获得CE标志产品的技术电子版文档，并负保管、保密和提交当局的责任。该文档至少保存至最后一批产品停产五年后。一旦欧盟主管当局需要获得CE标识产品的技术文件（含已备案的技术文件的新版本），乙方负责在10个工作日内递交欧盟主管当局。

2.3 Party B would not be responsible for the file content. All the documents, such as sales list and complain records are deemed confidential information; Party B have the obligation to send them to competent authority if necessary. Part B should maintain and keep them secret.

乙方不对甲方提交的文件内容负责，乙方对甲方提供的销售清单、投诉记录等文件，负责递交欧盟相关机构审阅并负有保管、保密的责任。

2.4 Party B permits Party A to use part B's name and address for the purpose of inclusion/printing on all packaging, labeling and instruction for use, of products that carry CE Marking and that have been represented by Party B.
乙方允许在被乙方代表的加贴CE标志的甲方产品的包装、标签、说明书、宣传册等上面加印乙方名称地址作为甲方的欧盟授权代表。

2.5 Party B shall keep following files of party A's products with CE mark at the disposal of the national authorities, at least five years after the last batch product's manufacturing. Minimum documents are:
1) Declaration of conformity,
2) Copy of the label, packaging and instructions for use (in all languages requested by the countries where the device is marketed),
3) Notified Body certificate (where relevant),
4) Post market surveillance process and data, vigilance reports and complaints, processes and data,
5) Technical documentation relevant to market surveillance investigation being undertaken by the Member State,
6) Relevant clinical data / notification,
7) Details of any distributors / suppliers putting the CE marked devices on the market,
8) Incident reports and corrective actions taken.
乙方应保留甲方以下与CE 标志产品有关的资料供主管当局使用， 至少保存至最后一批产品出厂后五年。这些资料至少应包括：
1)符合性声明
2)标签、包装、说明书副本（所有上市国家要求的语言的版本）
3)公告机构证书（适用时）
4)上市后监督过程和数据、警戒报告以及投诉、处理和数据
5)与欧盟成员国上市监督调查有关的技术文件
6)相关的临床数据/通知
7)经销甲方CE标志医疗器械的经销商/供方细节
8)事故报告及采取的纠正措施

2.6 Party B must keep Party A informed in all matters that may be connected to the devices placed on the market in the EU. At the minimum, the exchange of information concerning following shall be covered.
乙方应通知甲方所有有关其在欧盟上市医疗器械的信息，至少包括:

2.6.1Safeguard Clause保护条款
"Where a Member State ascertains that a medical devices, when correctly installed, maintained and used for their intended purpose may compromise the health and/or safety of patients, users or, where applicable, other persons, or the safety of property, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service."
If the relevant Competent Authority contacts the Party B about its interim measures to withdraw Party A's device(s) from the market or prohibit or restrict their being placed on the market or put into service, Party B should immediately communicate such measures to Party A and advise Party A as to the implications of this decision.
When the Commission finds that national measures taken under the Safeguard Clause "are unjustified, it shall immediately so inform the Member State which took the measures and the manufacturer or his authorized representative".
If the relevant Competent Authority contacts Party B, Party B should immediately communicate such information to Party A and advise Party A as to the implications of this decision.
"当一个成员国确信一个医疗器械在正确安装、维护和按照预期用途使用情况下，可能会危害患者、使用者、（适用时）其他人员或财产的健康和/或安全时，应采取所有适当的临时措施以

将医疗器械撤出市场、禁止或限制器上市”。
如果有关主管当局就有关对甲方医疗器械采取撤出市场、禁止或限制上市的临时措施联系乙方，乙方应立即将相关措施与甲方沟通，并向甲方建议此决定的相关影响。
当欧盟委员会认为国家的措施不合理，应立即通知采取措施的成员国、制造商或其欧盟授权代表。
如果有关主管当局联系乙方，乙方应立即将相关措施与甲方沟通，并向甲方建议此决定的相关影响。

2.6.2警戒Vigilance
If the relevant Competent Authority contacts Party B about its assessment outcome of an incident of Party A's medical device, Party B should immediately communicate such information to the manufacturer and advise Party A as to the implications of this decision.
如果欧盟主管当局通知了乙方关于甲方产品发生的事故的决定，乙方应立即就此联系甲方并且使甲方知晓主管当局的决定。
Party B shall notify any information about the products with CE mark within boundary of E.U. to Party A, including any claims of customers and the competition company that produce the same CE marked products.
乙方应将获得的有关CE产品在欧盟境内的任何消息(包括客户投诉和同类竞争企业)及时通知甲方。

2.6.3If any accident/ near accident of products (CE marked products, premarket clinical investigation products and performance evaluation products) happens within boundary of E.U., Party B shall notify Party A within 3 working days after receiving the claims of customers and feedback about the product, and execute vigilance system of medical device products under the assisting of Party A, and also make initial report, investigation result and final report to competent authority of country in which the accident happens.
如果带有CE标志的产品，上市前临床试验的产品以及进行性能评估的产品在欧盟境内发生事故或者准事故，乙方应在收到或得知有关甲方产品的投诉或反馈信息3个工作日内及时通知甲方，并在甲方的协助之下调查原因，同甲方一起负责完成初始报告。乙方负责把完成的初始报告、调查结果和最终报告向欧盟主管当局提供。

2.7 Party B shall assist Party A to comprehending the condition of the same products within boundary of E.U, and send the related information to Party A in time.
乙方协助甲方了解欧盟市场同类产品的情况，并及时反馈给甲方。

2.8 Upon receiving the notice about the intention to carry out a clinical investigation for MDD or AIMDD, and the intention to carry out a performance evaluation for IVDD in EU, Party B shall notify communicate the information on the manufacturer and on the device to the Competent Authorities of the Member State in which he has his registered place of business. If any serious adverse events during clinical investigation, i.e. in the premarket phase, Party B Shall fully record and immediately notify to all Competent Authorities of the Member States in which the clinical investigation is being performed.
乙方需要在收到甲方关于在欧盟境内进行医疗器械和有源植入性医疗器械的临床试验计划，和体外诊断试剂的性能评估计划的通知后，需将相关信息通知所在国的主管机构CA。如果在临床调查中发生严重不良事件，乙方应及时对其进行完整记录并立即告知进行临床调查所在地的主管当局。

2.9 Party B shall appoint one or two persons as the primacy linkman whose responsibility is to connect with Party A and deal with the normal daily grind according to this agreement. The information of both Parties' linkman was written in appendix C.
乙方需指定一至二人，作为甲、乙双方的第一联络人，主要职责是与甲方共同协调、处理本协议条款规定范围内的日常工作。双方联络人的联络方式记录在本协议的附件（三）。

3. Jurisdiction & Duration 管辖权与有效期

3.1 This agreement is subject to the laws and jurisdiction of The Kingdom of Netherlands.
本协议是荷兰的法律制约和管辖。

3.2 This agreement is valid for the duration of **2024/5/25** and it becomes immediately effective from the signature date of Company A.
该协议自甲方签署之日起立即生效，有效期至2024/5/25。

3.3 During the implementation of the agreement, this agreement will be terminated automatically when:
在协议执行期间内，下列日期为本协议的自动终止日期：
1) The day upon Part A's CE Certificate be withdrawn temporarily, be closed or be recalled by the notified body.
甲方的CE证书因故被发证机构暂时吊销/关闭/收回之日；
2）Party A can not provide the required technical file to Party B within 30 days after approval of the CE certification or before using CE mark for "self declaration" products. During 60 days from the date of this agreement terminated, Party A could transact the routine affairs as the authorized European Representative while Party A could appoint new European Representative and change the CE certification. Party B should report the invalid agreement to the notify body for record.
甲方在认证结束取得证书之后的30天内，或者"自我声明"产品在使用CE标记之前，仍然没有提供给乙方符合要求的CE技术文档的，本协议自动失效。在本失效之日起的60天内，为了能够方便甲方聘请新的欧盟代表及更改CE证书等相关工作，乙方可以代为继续行使欧盟代表日常事务。乙方应该将与甲方失效的协议信息及时报公告机构备案。
3）Party A doesn't payoff the service fee according to this agreement and refuse to explain on the deadline.
甲方没有按协议规定的最后期限内付清欧盟代表服务费用，又不作解释的。

Company A: 2024年4月29日 / Date　　Signature

Company B: 2024.4.29 / Date　　Signature

SUNGO Europe B.V. COMMON SEAL

Appendix A

For the following product categories:
申请CE认证的产品名称：

No.	Product name 产品名称	Product classification 产品分类	Product name in Chinese 中文名称
1	**Disposable medical mask (Non-sterile)**	**Class I**	一次性使用医用口罩（非灭菌）
2			
3			
4			
5			
6			

Appendix B

提交欧盟代表的《技术文件目录》

	Contents	文件清单
Part A		
1	Name, Postal Address of Manufacturer/ EU Representative	制造商和欧洲代表的名字、地址
2	A listing of all manufacturing sites covered by the quality system	质量体系所涉及的全部制造场所清单
3	Product description	产品描述
3.1	Product name, classification of the device and accessories	产品名字、器械及附件的分类
3.2	List of accessories (if applicable)	产品附件清单（适用时）
3.3	Specification, model and article numbers	规格、型号及货号
3.4	Chosen conformity assessment path	符合性评价路径
3.5	Intended use	预期用途描述
3.6	Integral parts of the sales unit	主要的销售单元（适用时）
3.7	A brief product history (including existing regulatory approvals)	简要的产品历史（包括现有的管理审批）
4	List of harmonized standards	适用的标准清单
5	Essential Requirements checklist	基本要求检查表
6	Overall manufacturing and inspection plan of the product	产品的总体生产或质量控制方案
7	Risk analysis	风险分析
8	Clinical report	临床报告
9	Labelling, inl. Product labels and package labels	标签，包括产品标签、包装标签
10	Instruction for use, patient information, advertising material	使用说明、患者信息、广告材料
11	Declaration of conformity	符合性声明
Part B		
12	Information concerning the quality system specific to the product	与产品有关的质量体系的信息
13	Detailed descriptions of the product	详细的产品描述
13.1	Design drawings and product specifications	设计图及产品技术规范
13.2	Packaging and specification	包装条件及规格
13.3	Description of the manufacturing processes	生产过程描述
13.4	Raw materials and suppliers	原材料和供方
14	Test, verification and evaluation report	试验、验证及评估报告
14.1	Sterile method and validation	灭菌方法和验证的概述，灭菌证书（适用时）
14.2	Packaging verification (if applicable)	包装验证（适用时）
14.3	Chemical, physical and biology test, verification and evaluation report	化学、物理和生物学试验、验证或评估报告
15	Clinical datas	临床数据
15.1	Preclinical Evaluation, Expert Opinions	临床前评估，专家意见
15.2	Clinical plan	临床方案
15.3	Clinical datas	临床数据
15.4	Clinical Summary, Expert Opinions	临床总结，专家意见
15.5	Clinical report	临床报告
15.6	Relevant Literature	相关文献

A/B部分文件必须在需要时向欧盟代表处随时以书面或电子文档的形式提供最新版本；
Technical documents (the latest version) including Part A&B shall be submitted to the

EU representative in written or electronic form if required.
B部分文件不限于以上所列项目。Documents in SUNGO are not limited to the above-mentioned content.

Appendix C

《甲、乙双方第一通知人（联络人）以及联系方式》
Party A甲方: Guangzhou Dayun Medical Technology Co., Ltd.
Add地址: No. 632, Xintang Avenue, Xintang Town, Zengcheng Distrit Guangzhou, Guangdong, China
Contact联系人: Zhang Xiaoqin
Tel电话: +86（020）82453846
Mob手机: +8615011915352
E-mail邮箱: 980628779@qq.com

Party B乙方: SUNGO Europe B.V.
VAT：NL857821659B01
Add地址: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Contact联系人: SUNGO Secretary
Tel电话: +31(0)2021 11106
E-mail邮箱: ec.rep@sungogroup.com

备注事项：
甲、乙双方中的任何一方，一旦对上述信息做任何修改、调整或取消的，需书面/邮件方式及时通知对方。如果由于没有及时通知而造成一方的信息无法转达给另一方之错误的，由过错一方承担由此引起的相关责任。
If any of the above information is changed, adjusted or canceled, the manufacturer and EU REP shall inform the other party in email or written form without delay. If any mistake arise from one party failed to notify the other party timely, the related responsibility shall be undertaken by the guilty party.

Appendix D

《CE产品欧盟登记备案的条件、程序及提交的文件》Registration conditions, procedure and submissions

一、申请的前提条件：Prerequisites of Application

1.生产商已经取得CE证书的产品（或者自我声明/公告的产品），是否办理欧盟地区产品登记备案手续，由生产商视本企业CE产品出口欧盟地区的实际情况，自行决定是否需要办理此项手续。
The manufacturer who has obtained CE certificate（self declaration or issued by Notified Body) for their products may decide whether to go through the registration procedure according to the actual exporting situation in the European Union.

2.但是，如果生产商CE产品一旦有出口欧盟市场计划，且产品是以企业自己的名义出口欧盟市场的，根据欧盟对CE医疗器械产品的准入规定，生产商必须事先向欧盟代表提出申请，由欧盟代表代为提交所有的申请文件。这里所谓“以企业自己的名义出口欧盟市场”的含义是指：任何销售到欧盟地区的CE产品，在产品的任何之处（含产品内、外包装、说明书等），出现制造商任何信息的，既为“以企业自己的名义出口欧盟市场”，该企业的产品必须事先在欧盟申请办理登记备案手续。 否则，由此而引起的后果，由生产商承担。
But, if the manufacture plans to export products to EU market and exports in their own name, the manufacture shall apply to the EU REP firstly according to the CE product access rule of medical device, and then the EU REP shall submit all the application files. 'Export to the EU market in manufacturer's own name' means the manufacturer's information showed on any place (including product inside, outer package, operation manual, etc.) of any CE products exported to EU region. The product must apply for registration in EU region in advance. Otherwise, the resulting consequences shall be undertaken by the manufacturer.

3.如果在荷兰申请登记备案成功，原则上无需再向欧盟其他国家和地区申请办理相关产品的登记备案手续。If successfully registered in the Netherlands, in principle, there is no need to apply for the relevant product registration in other EU countries and regions.

二、申请的程序：Application procedure:

1.如果生产商决定为CE产品办理登记备案手续的，生产商应首先向欧盟代表提出申请并按规定提交所有相关登记备案材料和填写申请表格，经欧盟代表审核认可后由欧盟代表代为向荷兰卫生主管当局提交相关申请登记备案材料。If the manufacturer decides to register the CE products, the manufacturer shall firstly apply to their EU REP and submit all relevant materials including completed application forms. The EU REP shall review the documents and then submit them to the Netherlands Health administration Bureau for registration.

2.如果由于生产商提交的材料不齐备或有误被荷兰卫生医疗主管部门退回而延误登记备案的，由生产商按照要求修订、补充申请材料以后，由欧盟代表办理再次申请手续。If the submitted documents are not complete or have errors, the Netherlands Health administration Bureau will return the application and may cause delay of the registration. The manufacturer shall revise and supplement the application documents according to the requirements, and then re-apply the CE registration through EU REP.

3.目前，荷兰卫生主管部门对相关的登记备案信息，采取有条件的开放，即尚未开通对所有公众查询上述登记备案信息的平台。At present, the Netherland Health administration Bureau conditionally open the relevant CE registration information which means the CE registration information platform is not yet open to public.

三、办理登记所需要的文件（英文电子版本）：Registration required documents (electronic version in English)

1.企业的书面申请表格：（格式由欧盟代表统一提供）Application form(the format provided by EU REP)

2.CE证书：CE Certificate;

3.每一大类产品的CE技术文件：（除了PART A部分以外，临床数据、风险管理等内容是必需的；文件格式只接受电子PDF/JPG/TXT）：each product categories CE technical file (except Part A, Clinical data and risk management must be submitted; documents only accept electronic copy (PDF/JPG/TXT version).

4.产品最近的符合性声明（latest DECLARATION OF CONFORMITY）；
5.出口欧盟地区的销售清单；（格式由欧盟代表统一提供）Product sales list exported to EU market.(the format provided by EU REP)
6.企业合法拥有的商标或品牌的图案实样照片；Legally owned enterprise trademark or brand photos;
7.出口原包装实样和带CE标志产品标签的照片；Picture of exported product in original package and label with CE mark.
8.企业联系人及联络方式；企业网站地址。Contact information and website.

四、登记的撤消与失效：Withdraw and invalidation of registration
1.CE证书失效或因故被发证机构吊销、关闭、收回；CE certificate invalid or withdrew or canceled by releasing authority.
2.生产商、欧盟代表双方就《欧盟代表协议》的中止或失效；Termination or expiration of EC REP Agreement.
3.企业已登记备案产品，长期没有出口欧盟地区的记录；The product has been registered but there is no record of exporting to the EU region in a long-term.
4.其他。Others

认证证书 ◆ CERTIFICATE ◆ 认证证书 ◆ CERTIFICATE

POSI

CERTIFICATE

This is to certify that the Quality Management System of

Guangzhou Dayun Medical Technology Co., Ltd.

Business License Number: 91440101MA59N1EK50

Registered Address: South side of 1/F, Building B2, No. 632, Xintang Avenue, Xintang Town, Zengcheng District, Guangzhou, Guangdong, China
Audit Address: South side of 1/F, Building B2, No. 632, Xintang Avenue, Xintang Town, Zengcheng District, Guangzhou, Guangdong, China

applicable to

Production of Disposable Medical Masks

has been assessed and registered by POSI against the provisions of

ISO13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by POSI.
Please consult the website: www.posicert.com
The certificate information is also available on the CNCA official website: http://cx.cnca.cn.

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

General Manager

Certificate Registration No: 381200124R0S
Initial issue date: 2020.10.27 Issue date: 2020.10.27 Valid until: 2023.10.26

Shanghai POSI Certification Co., Ltd.
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CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

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Ons kenmerk:
CIBG-20201753

Bijlagen
-

Uw aanvraag
29 april 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 12 mei 2020
Betreft: aanmelding medisch hulpmiddel klasse I

Geachte heer Luo,

Graag bevestig ik hierbij de ontvangst op 29 april 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf Guangzhou Dayun Medical Technology Co., Ltd. met Europees gemachtigde SUNGO Europe B.V. onderstaand medisch hulpmiddel, ingedeeld in risicoklasse I, aflevert. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende dit product het bijbehorende kenmerk te vermelden.

Disposable medical mask(Non-sterile)
(geen merknaam) (NL-CA002-2020-50865)

Toekomstige wijzigingen in bovengenoemde gegevens – waaronder een eventuele wijziging van de indeling in risicoklasse in verband met wijzigingen van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voortschrijdend wetenschappelijk inzicht (zie art.9, lid 3 van Europese Richtlijn 93/42/EEG) – dient u te zijner tijd mede te delen.

Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling – verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Met name wijzen wij u op de Nederlandse-taaleis, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiesysteem.

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dhr. M.J. van de Velde