BIPSALUT

CERTIFICADOS MASCARILLA QUIRÚRGICA TIPO IIR

TQ IIR

- FICHA TÉCNICA DEL PRODUCTO
- TEST DE ENSAYO DEL PRODUCTO
- DECLARACIÓN DE COMFORMIDAD DEL COMERCIALIZADOR

POWER 4EVER S.L.
C/ DCT PUJADES 58 IGUALADA,
BARCELONA

BIPSALUT

FICHA TÉCNICA

MASCARILLA TRICAPA TIPO IIR QUIRÚRGICA

DESCRIPCIÓN Y COMPOSICIÓN

- *Modelo: TQ IIR*
- *Base de celulosa*
- *Sin fibra de vidrio*
- *Hipoalergénica*
- *Plana*
- *Plegable*
- *Color azul*
- *Barra de nariz adaptable*
- *Alta capacidad de filtración*
- *Ajuste perfecto*
- *Respetuoso con el medio ambiente*
- *Desechable*
- *No contiene látex*
- *Medidas 17,5 x 9,5 cm*

CARACTERÍSTICAS

- *Tipo de **protección** > 99 (BFE %)*
- *Mascarilla tricapa tipo IIR ≈ quirúrgica, para prevención respiratoria frente a partículas sólidas y líquidas del aire.*
- *Cumplen la norma UNE-EN 14683, que la clasifica como mascarilla tipo IIR, por su eficacia de filtración bacteriana (BFE) ≥ 99, presión diferencial <43, presión de resistencia a las salpicaduras ≥ 17 y limpieza microbiana 15 ufc/g.*

NORMA EU/ESP

- UNE EN 14683:2019+AC:2019
- ISO 22609: 2004

CE

CERTIFICADO DE ENSAYO
60382611 001

LIMPIEZA MICROBIANA (ufc/g)
15 ufc/g
EFICACIA DE FILTRACIÓN BACTERIANA (BFE), (Exhalación) (%)
99,90
EFICACIA DE FILTRACIÓN BACTERIANA (BFE), (Inhalación) (%)
99,90
PRESIÓN DIFERENCIAL (Pa/cm2) - (Respirabilidad)
29.9 Pa/cm2 +- 2 Pa/cm2
PRESIÓN DE RESISTENCIA A LAS SALPICADURAS (kPa)
1 de 32 a 17 kPa

Prüfbericht-Nr.: *Test Report No.*:	**60382611 001**	**Auftrags-Nr.** *Order No.*:	**168266786**	Seite 1 von 12 *Page 1 of 12*
Kunden-Referenz-Nr.: *Client Reference No.*:	N/A	**Auftragsdatum:** *Order date*:	May. 28, 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 (Non-sterile)			
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 receipt*:	May. 27, 2020
Prüfmuster-Nr.: *Test sample No.*:	20200413
Prüfzeitraum: *Testing period*:	May. 28, 2020 to Jun. 09, 2020
Ort der Prüfung: *Place of testing*:	See page 3
Prüflaboratorium: *Testing laboratory*:	TÜV Rheinland (Shenzhen) Co., Ltd.
Prüfergebnis*: *Test result**:	Pass

See Attachment: Photo documentation for details.

geprüft von / *tested by*:

Yazhen Xu Amanda Liu

Jun. 15, 2020 Yazhen Xu, Amanda Liu/ Engineer

Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

kontrolliert von / *reviewed by*:

Jun. 15, 2020 Angela Chen / Department Manager

Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

Sonstiges / *Other*:

- The test report consists of EN 14683 test report including this cover page (12 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*

Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens.
This test report only relates to the a. m. 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 test mark.
V04

EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No. ..... :	**60382611 001**
Date of issue ..... :	**See cover page**
Total number of pages ..... :	**See cover page**
Testing Laboratory ..... :	**TÜV Rheinland (Shenzhen) Co., Ltd.**
Address ..... :	1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, 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_A
Test Report Form Originator ..... :	TÜV Rh (SZ)
Master TRF ..... :	2020-03
Test item description ..... :	Disposable medical mask (Non-sterile)
Trade Mark ..... :	KUNKKA
Manufacturer ..... :	Same as the applicant
Model/Type reference ..... :	DY-01
Classification ..... :	Type IIR

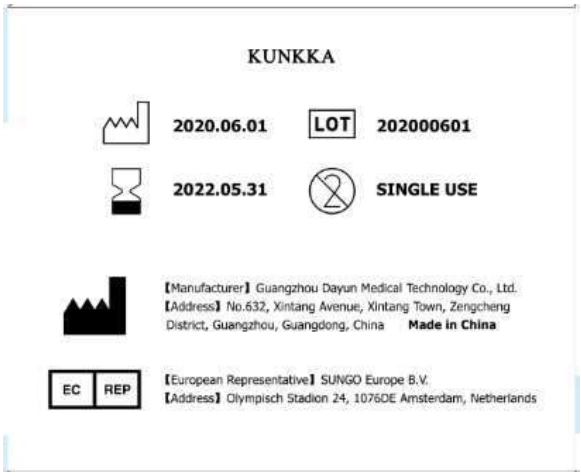
List of Attachments (including a total number of pages in each attachment):	
Attachment – Photo Documentation (3 pages)	
Summary of testing:	
Tests performed (name of test and test clause): Construction check according to: Clause 5.1.1 Materials and construction Clause 5.1.2 Design	**Testing location:** **TÜV Rheinland (Shenzhen) Co., Ltd.** 1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, 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)	**Pony Testing International Group** 2/3/4/6F., Building 35, No.680, Guiping Road, Xuhui District, Shanghai, 200233, China

Copy of marking plate

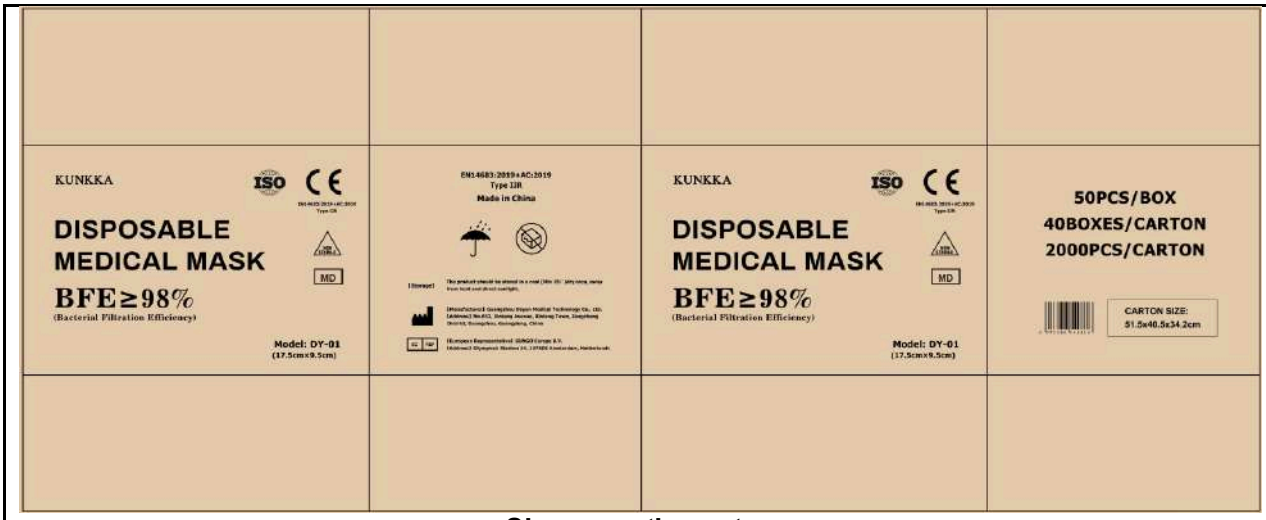
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Shown on the front package

Shown on the front package



Shown on the side package



Shown on the carton

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.	20200601
质 检 员 QC	QC01
检验日期 Inspection Date	2020年06月01日 1st of June, 2020
生产日期 Production Date	2020年06月01日 1st of June, 2020
有效期限 Expiry Date	2022年05月31日 31th of May, 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	广州市新塘镇新塘大道632号正华工业园 No.632, Xintang Avenue, Xintang Town, Zengcheng District, Guangzhou,Guangdong,China

Shown on the 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 polypropylene spunbond nonwoven and one layer of polypropylene 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**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
5.2.3	**Breathability**		**P**
	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**
20200413	**1**	**175×140**	**95.0**	**28.3**	**1920**	**0**	**99.90**	**--**
	2	**175×140**	**95.0**	**28.3**			**99.90**	**--**
	3	**175×140**	**95.0**	**28.3**			**99.90**	**--**
	4	**175×140**	**95.0**	**28.3**			**99.90**	**--**
	5	**175×140**	**95.0**	**28.3**			**99.90**	**--**

Supplementary information:
1, Each specimen was conditioned at 21.7 °C and 85.0 % 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**
20200413	1-1	29.9	29.1	8.0	--
	1-2	27.9		8.0	--
	1-3	28.1		8.0	--
	1-4	29.4		8.0	--
	1-5	30.4		8.0	--
	2-1	28.7	29.0	8.0	--
	2-2	28.2		8.0	--
	2-3	28.7		8.0	--
	2-4	30.2		8.0	--
	2-5	29.3		8.0	--
	3-1	29.1	29.2	8.0	--
	3-2	27.7		8.0	--
	3-3	30.9		8.0	--
	3-4	27.5		8.0	--
	3-5	30.8		8.0	--
	4-1	25.6	25.3	8.0	--
	4-2	26.1		8.0	--
	4-3	25.8		8.0	--
	4-4	25.2		8.0	--
	4-5	23.9		8.0	--
	5-1	30.2	30.3	8.0	--
	5-2	29.5		8.0	--
	5-3	31.5		8.0	--
	5-4	30.8		8.0	--
	5-5	29.7		8.0	--

Supplementary information:
Each specimen was conditioned at 21.7 °C and 84.6 % 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
20200413	**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, Each specimen was conditioned at 21.7 °C and 84.6 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.

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

3, Any technique used to enhance visual detection of synthetic blood: cotton absorbent swab.

4, The temperature and relative humidity for testing: 21.7 °C and 84.6 %.

5, Description of any pre-treatment techniques used: N/A.

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/g)**	**Remarks**	
20200413	**1**	**3.37**	**15**	**--**	
	2	**3.38**	**13**	**--**	
	3	**3.38**	**6**	**--**	
	4	**3.36**	**4**	**--**	
	5	**3.39**	**12**	**--**	
Supplementary information:					

End of EN 14683 test report

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(14.0cm×9.0cm), 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

DECLARACIÓN DE COMFORMIDAD

CE

POWER 4EVER SL, nombre comercial **BIP SALUT** en calidad de **COMERCIALIZADOR**, con domilcilio en C/Doctor Pujades 58 L-3 Igualada,Barcelona y provista con CIF nº B67627034 ;
declara bajo su responsabilidad que las siguientes referencias:

MASCARILLA TRICAPA CLASE I NO ESTERIL QUIRÚRGICA TIPO IIR

REFERENCIA DEL FABRICANTE: **DY-01**

REFERENCIA DEL COMERZIALIZADOR :**TQ IIR**

Objeto de la siguiente declaración, cumplen con los requisitos establecidos en la DIRECTIVA 93/42/CEE DEL CONSEJO de 14 de junio de 1993 relativa a los productos sanitarios.

CERTIFICADO Nº ENSAYO:
60382611 001

LABORATORIO ACREDITTADO:

TÜVRheinland®

Cumple con la norma:

EN 14683:2019+AC:2019

En Barcelona a 22 de Julio del 2020

BIPSALUT
POWER 4EVER SL
B 67627034

POWER 4EVER SL
C/ DOCTOR PUJADES 58 LOCAL 3
08700 BCN

BIPSALUT