统一社会信用代码

91450204MA5PAB206F（1-1）

营业执照

（副 本）

扫描二维码登录'国家企业信用信息公示系统'了解更多登记、备案、许可、监管信息。

名　　称　广西安然医疗器械有限公司

类　　型　有限责任公司(自然人投资或控股)

法定代表人　李文凯

经营范围　一类、二类、三类医疗器械生产及销售，劳保用品设计、生产、销售，食品、厨具卫具及日用杂品、化工产品（危险化学品除外）、卫生用品、家用电器、仪器仪表、橡胶制品、农副产品、服装服饰、日用品、针纺织品、文具用品、五金产品、办公设备、农产品、建筑材料销售，货物或技术进出口（国家禁止或涉及行政审批许可的除外），道路货物运输.（依法须经批准的项目，经相关部门批准后方可开展经营活动。）

注册资本　伍佰万圆整

成立日期　2020年02月21日

营业期限　长期

住　　所　柳州市柳南区银祥路1号3号厂房3-1

登记机关　柳州市柳南区市场监督管理局　4502011072251

2020　02　21

年　月　日

http://www.gsxt.gov.cn

市场主体应当于每年 1月1日 至 6月30日通过国家企业信用信息公示系统报送公示年度报告

国家企业信用信息公示系统网址:

国家市场监督管理总局监制

医疗器械生产许可证

企　业　名　称：广西安然医疗器械有限公司

社会信用代码：91450204MA5PAB206F

法定代表人：李文凯

企业负责人：李文凯

住　　所：柳州市柳南区银祥路1号3号厂房3-1

生产地址：柳州市柳南区银祥路1号3号厂房3-1

生产范围：
详见医疗器械生产产品登记表

有效期至　2021　年　03　月　31　日

许可证编号：桂食药监械生产许20200024号

日常监督管理机构：

日常监督管理人员：周德源；谭伟伟

投诉举报电话：12315

发证机关：广西壮族自治区药品监督管理局

签　发　人：韦广辉

2020 年 04 月01 日

国家药品监督管理局监制

国内天纺标GB2626-2006检测认证

CTTT-WT200121106-01

200215340010

检验报告

TEST REPORT

天纺标检测认证股份有限公司

TianFangBiao Standardization Certification & Testing Co.,Ltd

天纺标检测认证股份有限公司

200215340010

检 验 报 告

CTTT-WT20012106-01

Information Provided by Client	Applicant	Guangxi Anran Medical Equipment Co.,Ltd. Room 3-1,No.3,Workshop,No.1,Yinxiang Road,Liunan District,Liuzhou City	Contact Tel.	--- ---
	Manufacturer	---------- ----------		
	Information of Submitted Sample	Sample Name: Protective Mask KN95 Sample Count: 46Piece(s) Size: ---------- Quality Grade: ---------- Style No. or Order No.: AN RAN 9501A	Trademark: ---------- Colour: ---------- Safety Category: ----------	
Test Part Description		1# White Mask		
Test Type	Commission Test	Date of Submission: 2020-05-19	Date of Checking: 2020-05-26	
Test Standards	GB 2626-2006 Respiratory protective equipment —Non-powered air-purifying particle respirator			
Conclusion	Test results and compliance refer to next page(s). Stamp of Inspection Unit			
Non-standard Check Methods	----------			
Uncertainty of Result	----------			
Remarks	As per client's request that Filtration Efficiency is required to test only initial filtration efficiency and judged according to the standard GB 2626-2006. CNAS(L0608) authorizes the test item Filtration Efficiency, the test items Respiratory Resistance,Flammability,Dead Space,Appearance Inspection,View and Head Harness are unauthorized by CNAS(L0608). CMA(200215340010) authorizes all the test items.			Sample Attached Face side up

Approver 方倩 Checker 张涛 Editor

Test Items	Description	Unit	Standard Requirement	Results	Conclusions	Test Method/ Remarks
1#						
Respiratory Resistance	Total Expiratory Resistance	Pa	≤250	Samples Without Pretreatment: 1: 77 2: 69 Samples With Pretreatment: 1: 75 2: 70	Pass	GB 2626-2006
	Total Inspiratory Resistance	Pa	≤350	Samples Without Pretreatment: 1: 94 2: 85 Samples With Pretreatment: 1: 86 2: 84		
Flammability	---	---	Each part exposed to the flame shall not burn after it is removed from the flame; if it burns, the afterflame time shall not exceed 5s.	No continue burning	Pass	GB 2626-2006
Dead Space	CO_2 Volume Fraction in Inhalation	%	≤1	0.8	Pass	GB 2626-2006

Test Items	Description	Unit	Standard Requirement	Results	Conclusions	Test Method/ Remarks
Filtration Efficiency (KN95)	NaCl Particle	%	≥95.0	Initial Filtration Efficiency: Samples Without Pretreatment: 1: 99.01 2: 99.01 3: 98.93 4: 98.99 5: 98.93 6: 98.95 7: 99.01 8: 99.13 9: 99.06 10: 98.98 Samples With Pretreatment: 1: 99.80 2: 99.81 3: 99.81 4: 99.71 5: 99.74	Pass	GB 2626-2006
Appearance Inspection	Surface of The Sample	---	As per standard requirement	+	Pass	GB 2626-2006
	Component Material and Construction	---	As per standard requirement	+		
	Head Harness	---	As per standard requirement	+		
	The components after the temperature and humidity pretreatment	---	As per standard requirement	+		
	Label and the information provided by manufacturer	---	As per standard requirement	+		
View	View Below	°	≥60	62	Pass	GB/T 2891-1995

Test Items	Description	Unit	Standard Requirement	Results	Conclusions	Test Method/ Remarks
Head Harness	Disposable Facepiece	---	Each head harness, buckle and other adjustment components of the mask should not have slippage or breaking for 10s under 10N loading.	The head harness have no slippage or breaking for 10s under 10N loading	Pass	GB 2626-2006

+ Meet the standard requirements, X Not Meet the standard requirements.

Blank Part Below

Sample

FDA

Fiscal Year 2020

This certifies that:

GUANGXI ANRAN MEDICAL EQUIPMENT CO.,LTD
PLANT 3-1.NO.3 AND NO.1 YINXIANG ROAD,LIUNAN DISTRICT, LIUZHOU CITY, GUANGXI 545001, CHINA

Was registered with US Food and Drug Administration, Center for devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807.

Registration of FEI Number: 3016665963
Owner/Operator Number: 10064406

Listing Number	Premarket Submission Number/Type	Device Class	Product Codes	Activities
D379015	Exempt	ACCESSORY, SURGICAL APPAREL	LYU	Manufacturer
D384876	Enforcement Discretion	Face mask (except N95 respirator) for general Public / healthcare personnel per IIE guidance	QKR	Manufacturer

FDA Owner/OPERATOR NUMBER QUERY and Registration Number URL: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding". The U.S. Food and Drug Administration does not issue a certificate of registration, This file is used as FDA company information display only.

Issued: March 26, 2020

Expiration Date: Dec 31, 2020

Address: Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Contact Number: 1-888-INFO-FDA
(1-888-463-6332)
https://www.fda.gov

Help (./help/index.html)

DRLM Home (mainMenu.htm) > Change Registration Information for a Facility

✔ Facility

✔ Products Listing

Update Registration Successful

Facility: GUANGXI ANRAN MEDICAL EQUIPMENT CO.,LTD , liuzhou city , Guangxi, CHINA

Registration/FEI Number: 3016665963/3016665963

The Owner/Operator Number for this Registration is: 10064406.

Facility Information

Registration Number:
3016665963

Initial Importer:
N

Facility Name:
GUANGXI ANRAN MEDICAL EQUIPMENT CO.,LTD

Address:
plant 3-1.NO.3 and NO.1 yinxiang road,liunan district,
liuzhou city, Guangxi, 545001, CHINA

DUNS Number:

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):

Owner/Operator Information

Owner/Operator Number:
10064406

Contact Name:
Jie Tan

Company:
GUANGXI ANRAN MEDICAL EQUIPMENT CO.,LTD

Address: plant 3-1.NO.3 and NO.1 yinxiang road,liunan district
liuzhou city, GUANGXI, 545001, CHINA

Telephone:
86 - 0772 - 2800650

Fax:
-

E-mail: guangxianran@nmpa-cn.com

DUNS Number:

Official Correspondent Information

Contact Name:
Jie Tan

Company:
GUANGXI ANRAN MEDICAL EQUIPMENT CO.,LTD

Address: plant 3-1.NO.3 and NO.1 yinxiang road,liunan district
liuzhou city, GUANGXI, 545001, CHINA

Telephone:
86 - 0772 - 2800650

Fax:
-

E-mail: guangxianran@nmpa-cn.com

DUNS Number:

United States Agent Information

Contact Name:
Jack Zhang

Contact Title:
Mr

Business Name:

Address: 1942 Broadway St. , STE 314C
Boulder, Colorado, 80302, UNITED STATES

Phone:
720 - 7791888

Fax:

DUNS Number:

E-mail: us.fw@fda-registered.com

Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers
D384876	Enforcement Discretion	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance	Manufacturer	
D379015	Exempt	MSH	Respirator, surgical	Manufacturer	

Date of Initial Registration: 2020-03-25 11:21:31.0

澳大利亚TGA

Australian Government

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Thirty Four Degrees South Import Agencies Pty Ltd

for approval to supply

Thirty Four Degrees South Import Agencies Pty Ltd - Public N95 respirator

ARTG Identifier	334935
ARTG Start date	23/04/2020
Product Category	Medical Device Included Class 1
GMDN	57793
GMDN Term	Public N95 respirator
Intended Purpose	A disposable, single use mask to cover nose and mouth to help protect medical personnel from airborne pathogens while they are in contact with or near patients.

Manufacturer Details	Address	Certificate number(s)
Guangxi Anran Medical Equipment Co Ltd	Plant 3-1 No 3 and No 1 Yinxiang Road Liunan District Liuzhou City, Guangxi, 545001 China	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

· - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Public N95 respirator

Product Specific Conditions

No specific conditions have been recorded against this entry.

Australian Government

Department of Health

Therapeutic Goods Administration

Record Summary

334935 Thirty Four Degrees South Import Agencies Pty Ltd - Public N95 respirator

Sponsor	Thirty Four Degrees South Import Agencies Pty Ltd
Therapeutic Type	Medical Device
Product Category	Included Class 1
ARTG Start date	23/04/2020
Postal Address	221/180 Campbell Parade, Bondi, NSW, 2026 Australia
Billing Address	221/180 Campbell Parade, Bondi, NSW, 2026 Australia

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address	Certificate number(s)
Guangxi Anran Medical Equipment Co Ltd	Plant 3-1 No 3 and No 1 Yinxiang Road Liunan District Liuzhou City, Guangxi, 545001 China	

Products

1.Public N95 respirator

Product Type	Single Device Product	**Status**	Current
		Effective date	23/04/2020

GMDN	57793 Public N95 respirator
Functional description	Not included on record
Intended purpose	A disposable, single use mask to cover nose and mouth to help protect medical personnel from airborne pathogens while they are in contact with or near patients.
Variant information	

Device Information

Record Summary

比利时国家Mensura实验室认证

Rapport - Alternative Test Protocol voor type FFP2/FFP3 maskers in kader van COVID-19

Test van Type FFP2 mondmaskers volgens het ATP ontwikkeld door Groep IDEWE in samenwerking met de FOD economie

Erkend voor ATP door FOD Economie

Uitvoerder: **Mensura Consult**
Gaucheretstraat 88 / 90
1030 Brussel
KBO: 873.758.677

Specificaties testapparatuur

TSI Portacount 8038 met N95 module en TSI Particle Generator 8026

Randvoorwaarden

De maskers werden onderworpen aan het Alternatieve Test Protocol (ATP) - dd. 09/06/2020

Dit testprotocol is een korte procedure die een snelle beoordeling van maskers toelaat om maskers vrij te geven of af te keuren als FFP2 in functie van de huidige tekorten aan FFP2 maskers in het kader van de COVID-19 crisis. De ATP geeft een indicatie over de mate waarin het masker geacht mag worden te voldoen aan de EN-149 of gelijklopende buitenlandse normen. Het masker kan afgekeurd worden of vrijgegeven worden al dan niet met bijkomende gebruiksvoorwaarden (zie conclusies testfases)

De test werd door **Mensura Consult** met de nodige zorg uitgevoerd conform het door FOD Economie opgestelde ATP protocol.

Het resultaat blijft indicatief, de omstandigheden waarin de maskers zullen gebruikt worden blijft de verantwoordelijkheid van de opdrachtgver van deze test.

Ondertekening

Ir. Karine Eerdekens
Lead Transformation Officer
Directeur Risicobeheersing – Directeur Gestion des Risques
Mensura EDPB/SEPP

Aanvrager

Identificatie - Aanvrager

o Naam	**HUANG TRADING BVBA**			
o Straat	HUANG TRADING BVBA			
o Postcode	2100	Gemeente	Deurne	
o Uw Externe Dienst voor Preventie en Bescherming - *klik keuze aan*				
o KBO / BTW nr	BE0632542740	**Belangrijk - Invullen aub**		
o PO nummer				

Contactpersoon - Aanvrager

o Naam :	HUANG BAO BEI
o E-mail :	huangtradingco@gmail.com / info@nvpconsult.be
o Telnr of gsmnr :	0485 62 78 19

Contactpersoon - Verzending ATP rapport

o Naam :	HUANG BAO BEI
o E-mail :	huangtradingco@gmail.com / info@nvpconsult.be
o Telnr of gsmnr :	0485 62 78 19

Facturatiegegevens

o Naam :	HUANG TRADING BVBA
o IBAN nr.	BE44 3631 4867 2445
o BIC	BBRUBEBB

Een duidelijke omschrijving van te testen masker

Commerciële benaming - Masker Type 1

o Merk	**CHOUPETTE**
o Model	**Protective mask KN95**
o Type	**KN95**
o EAN nummer *(indien aanwezig):*	
Gegevens van de fabrikant	**Guangxi Anran Medical Equipment CO, LTD**

Eindresultaat

FFP2 TAPE NOSE volgens ATP

mensura

Rapport ATP voor type FFP2 maskers

Identificatie - Aanvrager

Naam	**HUANG TRADING BVBA**
Contactpersoon	**HUANG BAO BEI**
Uw ref masker	**HT 1**

Omschrijving van te testen masker

o Merk	**CHOUPETTE**
o Model	**Protective mask KN95**
o Type	**KN95**
o EAN nummer *(indien aanwezig):*	**0**

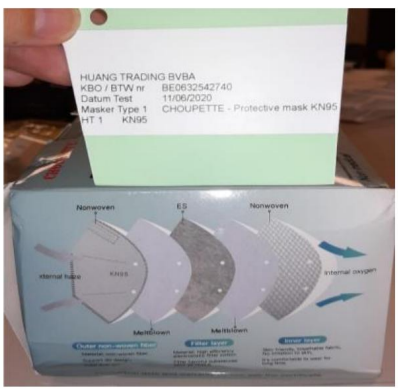
Gegevens van de fabrikant	**Guangxi Anran Medical Equipment CO, LTD**
Resultaat test	**FFP2 TAPE NOSE volgens ATP**

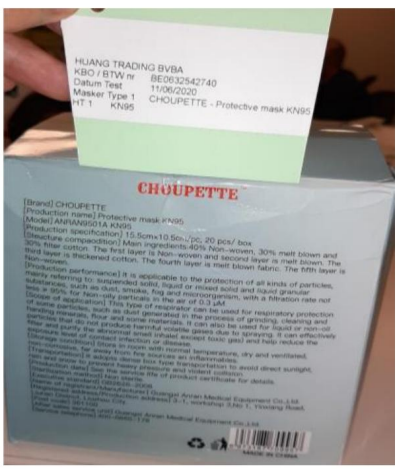
Toestel gebruikt voor ATP test TSI PortacCount 8038 met N95 module en Particle Generator 8026

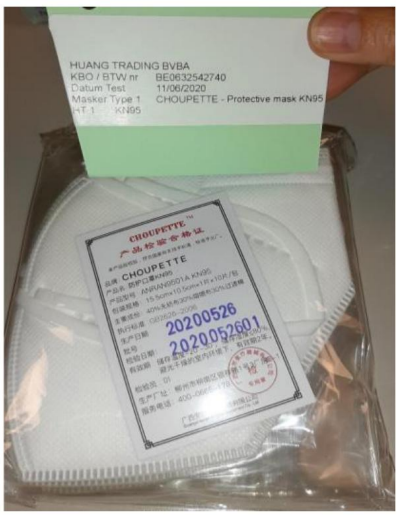
Locatie: Antwerpen	Toestel - Serienr.	8038201620	**Certificaat**
Limburg	Toestel - Serienr.	8038201529	**Certificaat**
Brussel	Toestel - Serienr.	8038201629	**Certificaat**

Datum test	11/06/2020
Locatie	Antwerpen
Zaal	DEK

Foto's Masker & Verpakking

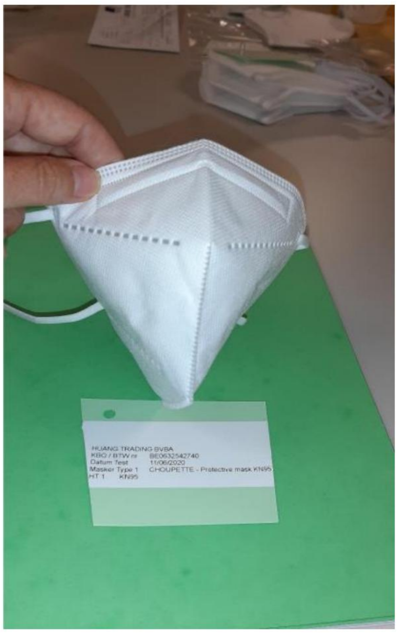


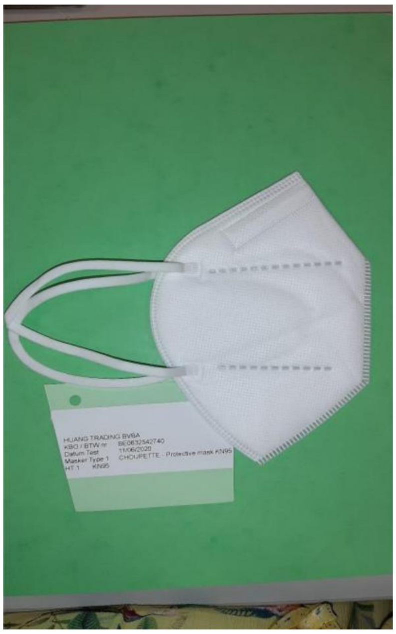





HUANG TRADING BVBA
KBO / BTW nr BE0632542740
Datum Test 11/06/2020
Masker Type 1 CHOUPETTE - Protective mask KN95
HT 1 KN95


HUANG TRADING BVBA
KBO / BTW nr BE0632542740
Datum Test 11/06/2020
Masker Type 1 CHOUPETTE - Protective mask KN95
HT 1 KN95


HUANG TRADING BVBA
KBO / BTW nr BE0632542740
Datum Test 11/06/2020
Masker Type 1 CHOUPETTE - Protective mask KN95
HT 1 KN95


HUANG TRADING BVBA
KBO / BTW nr BE0632542740
Datum Test 11/06/2020
Masker Type 1 CHOUPETTE - Protective mask KN95
HT 1 KN95


KN95
HUANG TRADING BVBA
KBO / BTW nr BE0632542740
Datum Test 11/06/2020
Masker Type 1 CHOUPETTE - Protective mask KN95
HT 1 KN95


KN95
HUANG TRADING BVBA
KBO / BTW nr BE0632542740
Datum Test 11/06/2020
Masker Type 1 CHOUPETTE - Protective mask KN95
HT 1 KN95

Volgens ATP - Protocol versie 09/06/2020

TESTFASE A - Deeltjespenetratietest van het filtrerend membraan van het masker

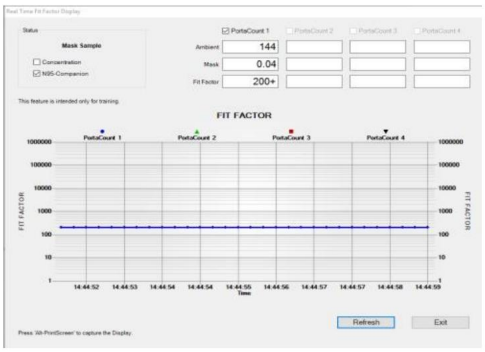
Fase A2 - bepaling nominale filterpenetratie NFPn% — **module N95 ingeschakeld**

Masker 1

	Masker	Omgeving	NFPn%		
Testgegevens	0,04	148	**0,03**	**Tester:**	MDB
				Testpersoon:	GS

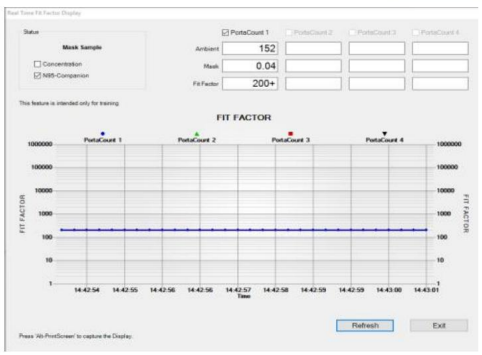
Masker 2

	Masker	Omgeving	NFPn%		
Testgegevens	0,04	144	**0,03**	**Tester:**	MDB
				Testpersoon:	MB



Masker 3

	Masker	Omgeving	NFPn%		
Testgegevens	0,04	152	**0,03**	**Tester:**	MB
				Testpersoon:	MDB



Toelichting over mogelijke resultaten NFPn %

3 maskers : NFPn% > 0,5%	**STOP - Niet geslaagd voor ATP**	
3 maskers : NFPn% < 0,05 %	**Testfase B1 - 6 maskers testen - globale fitfactor k 30 test**	X
In alle andere gevallen	**Testfase B1 - 6 maskers testen - globale fitfactor k30/k50**	

TESTFASE B - Beoordeling van de inwaartse lek op basis van vereenvoudigde fittesten — **module N95 ingeschakeld**

Globale fitfactor k 30 - masker 1 - 2 - 3

Testfase B1 - 3 maskers - fittest bij normaal dragen

Testpersoon GS

Masker 1

Stap 1: Normaal in- en uitademen	2
Stap 2: Links en rechts draaien hoofd	2
Stap 3: Tekst lezen	4
Stap 4: Vooroverbuigen	2
Globale fitfactor k	**2**

Testpersoon MB

Masker 2

Stap 1: Normaal in- en uitademen	2
Stap 2: Links en rechts draaien hoofd	2
Stap 3: Tekst lezen	4
Stap 4: Vooroverbuigen	2
Globale fitfactor k	**2**

Testpersoon MDB

Masker 3

Stap 1: Normaal in- en uitademen	4
Stap 2: Links en rechts draaien hoofd	5
Stap 3: Tekst lezen	9
Stap 4: Vooroverbuigen	3
Globale fitfactor k	**4**

Testpersoon GS

Masker 4

Stap 1: Normaal in- en uitademen	1
Stap 2: Links en rechts draaien hoofd	1
Stap 3: Tekst lezen	3
Stap 4: Vooroverbuigen	1
Globale fitfactor k	**1**

Testpersoon MB

Masker 5

Stap 1: Normaal in- en uitademen	2
Stap 2: Links en rechts draaien hoofd	3
Stap 3: Tekst lezen	4
Stap 4: Vooroverbuigen	3
Globale fitfactor k	**3**

Testpersoon MDB

Masker 6

Stap 1: Normaal in- en uitademen	6
Stap 2: Links en rechts draaien hoofd	5
Stap 3: Tekst lezen	6
Stap 4: Vooroverbuigen	4
Globale fitfactor k	**5**

Testfase B1 - masker 1 tot 6 : minstens 5 maskers k ≥ 30 ?

Neen : Testfase B2 - 3 extra maskers fittest Tape Nose

Testfase B2 - 3 maskers - fittest Tape Nose

Masker 1

Stap 1: Normaal in- en uitademen	117
Stap 2: Links en rechts draaien hoofd	92
Stap 3: Tekst lezen	146
Stap 4: Vooroverbuigen	138
Globale fitfactor k	**119**

Masker 2

Stap 1: Normaal in- en uitademen	200
Stap 2: Links en rechts draaien hoofd	200
Stap 3: Tekst lezen	200
Stap 4: Vooroverbuigen	46
Globale fitfactor k	**109**

Masker 3

Stap 1: Normaal in- en uitademen	91
Stap 2: Links en rechts draaien hoofd	69
Stap 3: Tekst lezen	194
Stap 4: Vooroverbuigen	60
Globale fitfactor k	**85**

Masker 4

Stap 1: Normaal in- en uitademen	43
Stap 2: Links en rechts draaien hoofd	37
Stap 3: Tekst lezen	62
Stap 4: Vooroverbuigen	48
OVERALL Globale fitfactor k	**46**

Masker 5

Stap 1: Normaal in- en uitademen	200
Stap 2: Links en rechts draaien hoofd	200
Stap 3: Tekst lezen	200
Stap 4: Vooroverbuigen	200
Globale fitfactor k	**200**

Masker 6

Stap 1: Normaal in- en uitademen	32
Stap 2: Links en rechts draaien hoofd	50
Stap 3: Tekst lezen	92
Stap 4: Vooroverbuigen	15
Globale fitfactor k	**31**

Testfase B2 - masker 1 tot 6 : minstens 5 maskers k ≥ 30 ?

Ja : masker Tape Nose volgens ATP - score 2

Synthese

ATP resultaat	Testfase A - A2 (N95 aan) NFPn%	Testfase B1 - Normaal (N95 aan) Globale fitfactor k	Score B1	Testfase B2 - Tape Nose (N95 aan) Globale fitfactor k	Score B2	Prioriteitenscore R
Masker 1 - tp1	0,03	2	0	119	2	2
Masker 2 - tp2	0,03	2	0	109	2	2
Masker 3 - tp3	0,03	4	0	85	2	2
Masker 4 - tp1		1	0	46	2	2
Masker 5 - tp2		3	0	200	2	2
Masker 6 - tp3		5	0	31	2	2
Evaluatie						2,0

Berekening Prioriteitenscore R - gemiddelde van 6 scores	
R - 1 tot 1,4	FFP2 volgens ATP
R - 1,5 tot 2,2	FFP2 Tape Nose
R - 2,3 tot 3	FFP2 Tape All

Eindresultaat Masker **FFP2 TAPE NOSE volgens ATP**

Er kan aan de hand van de documentatie niet worden aangetoond dat de maskers conform zijn, maar het resultaat van de test volgens het ATP is positief.
De pasvorm (fit) van de maskers is echter niet goed genoeg ter hoogte van de neusbrug:
De maskers moeten tijdens het gebruik worden afgeplakt ter hoogte van de neusbrug.
De maskers worden vrijgegeven als FFP- maskers.
Op de verpakking wordt volgende waarschuwing aangebracht:

Aanbevelingen voor het gebruik van maskers

Bij de keuze van FFP2-maskers geldt steeds volgende hiërarchie:
1° keuze: maskers met een volledige attestering volgens EN149
2° keuze: maskers uit de categorie "FFP2 geslaagd volgens ATP"
3° keuze: maskers uit de categorie "FFP2 Tape nose volgens ATP"
De beste beschikbare keuze wordt ook steeds voorbehouden voor risicoafdelingen mbt COVID-19.
Maskers die ingedeeld werden in de categorie "FFP2 tape all volgens ATP" zijn maskers die goed filtermateriaal hebben, maar die omwille van de

Voor het masker wordt bijkomend een **prioriteitenscore** berekend die toelaat om binnen de betreffende indelingscategorie een optimale keuze
R is een getal dat tussen 1 en 3 ligt.

Keuzes binnen de categorie-indeling op basis van prioriteitenscore:
FFP2 volgens ATP – R van 1 tot 1,4 – kies masker met de score dichtste bij 1
FFP2 tape nose – R van 1,5 tot 2,2 – kies masker met score dichtste bij 1,5

Archief


HUANG TRADING BVBA
KBO / BTW nr BE0632642740
Datum Test 11/06/2020
Masker Type 1 CHOUPETTE - Protective mask KN95
HT 1 KN95

Legende

Testfase A: Deeltjespenetratiestest van het filterend membraan van het masker

Fase A2: Inschatting van de nominale filterpenetratie (NFPg%) op basis van filterpenetratie van deeltjes tussen 20 en 60 nm (NFPn%). Dit gebeurt met behulp van een Portacount voorzien van een deeltjesteller met een N95 module op 3 maskers die volledig afgesloten worden op het gezicht van een testpersoon (meting bij N95 module ingeschakeld).

Fase A1: Bepaling van de maximale penetratie (%) volgens normen EN 13274-7 / EN 149 §8.11 op 3 maskers.

Testfase B: Beoordeling van de inwaardse lek op basis van vereenvoudigde Fittesten

6 Maskers worden getest (3 verschillende testpersonen aan 2 maskers per persoon)

Fase B1 - Fittest bij normaal dragen masker

Fase B2 - Fittest Tape Nose

NFPn%
Nominale filterpenetratie, dit betekent dat we de kwaliteit van het filtermateriaal gaan bekijken voor de deeltjes met een grootte van 0.02µm tot 0.06µm

NFPg%
Globale filterpenetratie, dit betekent dat we de kwaliteit van het filtermateriaal gaan bekijken voor verschillende groottes van deeltjes, **niet enkel** die van 0.02µm tot 0.06µm

N95-aan vs. N95-uit
Deze is een module op ons toestel die ons toelaat om te gaan kijken specifiek naar de deeltjes met eerder vermeldde grootte van 0.02µm tot 0.06µm. Als deze module aan staat kijken we enkel naar deeltjes met deze grootte. Staat de module uit, kijken we naar een breder spectrum van deeltjesgroottes.

丹麦GTS测试CE报告（非油性）

Test Reg. nr. 8

Guangxi Anran Medical equipment Co., Ltd.
Room 3-1, No 3, Workshop, No 1, yinxiang Road,
Liunan District, Liuzhou city, Guangxi Province,
China

Brøndby, 29 June 2020
120-26884

rafb/szp

Test Report

Guangxi Anran Medical Equipment Co., Ltd.

Rasmus Forsberg
2020-06-29

Digitally signed by Rasmus Forsberg
rafb@force.dk
Specialist

Sarah Pedersen
2020-06-30

Digitally signed by Sarah Pedersen
szp@force.dk
Project Manager

The report is only valid with two digital signatures from FORCE Technology. The original version of the report is archived in FORCE Technology's database and is sent in electronic duplicate to the customer. The stored version of the report at FORCE Technology prevails as documentation for its contents and validity.

GTS ADVANCED TECHNOLOGY GROUP

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Test report

Object: Test of mask AN RAN 9501A

Samples received: 11.05.2020

Sampling by: Guangxi Anran Medical Equipment Co., Ltd.

Method: RFU 02.075 version 2

Test date: 20.05.2020-26.06.2020

Results:

§ 8.2 Visual inspection

The mask was of uniform light white material and without valve. The mask had white straps that fit around the ears and was marked "KN95"

§ 8.4 Practical performance

Practical performance was performed by one test subject in accordance with the specifications in RFU 02.075 version 2.

	Comments
a) Head harness comfort	Comfortable fit and soft elastics
b) Security of fastenings	Ok but had to tie a knot as the straps did not have any means of adjustment
c) Field of vision	Ok
d) Maintenance of face seal	Ok
e) Other comments	

Table 1: Practical performance.

§ 8.7 Carbon dioxide content of the inhalation air

Three test fits of the mask were measured. The average was 0,39%. The requirement in EN 149 is <1,0%.

§ 8.9 Breathing Resistance

The requirements of EN 149:2001 + A1:2009 is listed in the table below.

Sample	Result (mbar)	Requirements (mbar)	Parameter
AN RAN 9501A	0,40 1,37 2,23	<0,7 <2,4 <3,0	(Inhalation, 30 l/min) (Inhalation, 95 l/min) (Exhalation, 160 l/min)

Table 2: Breathing resistance

§ 8.11 Penetration of filter material

The requirements of EN 149:2001 + A1:2009 is listed in the table below. All results are an average of 3 masks.

Sample	Result (%)	Requirements (%)	Aerosol
AN RAN 9501A	1,61	<6	Sodium chloride, 95 l/min

Table 3.1: Penetration of filter material: Initial penetration

Sample	Result (%)	Requirements (%)	Aerosol
AN RAN 9501A	2,11	<6	Sodium chloride, 95 l/min

Table 3.2: Penetration of filter material: Maximum penetration during exposure

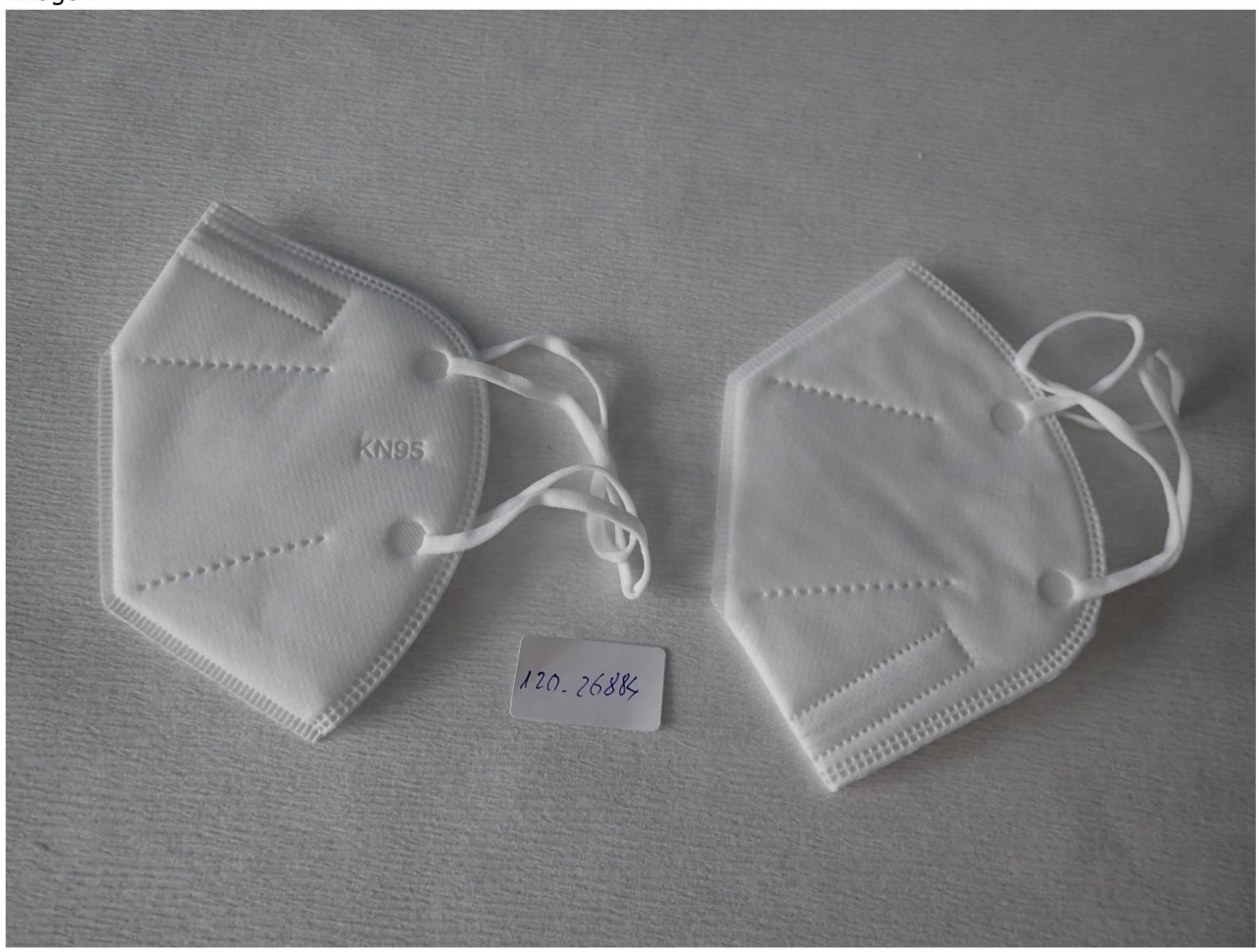
Conclusion:

The mask complies with the requirements of RFU 02.075 version 2 for the tests performed in this report.

Image 1:


KN95
Disposable protective mask
AN RAN
In line with national standards
GB2626-2006 KN95
Wear Instructions
120-26884
20 pre boxes

Image 2:



FORCE Technology - Terms and Conditions

Test, calibration and product approval

1. PREAMBLE

1.1 FORCE Technology ("FORCE") registration no. 55117314 is a GTS institute (in Danish: "Godkendt Teknologisk Servicevirksomhed"). FORCE is an approved technological service institution, organised and existing under the laws of Denmark with its registered office at Park Allé 345, 2605 Brøndby, Denmark.

1.2 In these Terms and Conditions ("Conditions"), Customer means the counterparty to the Agreement.

1.3 These Conditions constitute an integral part of the Agreement concluded between FORCE and the Customer ("the Parties"), including any quotations from FORCE and/or purchase orders from the Customer.

1.4 Any deviation from or amendments to individual provisions of FORCE's Conditions have no effect unless expressly agreed upon in writing, signed by an authorized representative of each Party and provided the deviation/amendment is clearly specified.

1.5 The Customer's prospective general terms and conditions is not accepted by FORCE irrespective whether the Customer sends such general terms and conditions to FORCE after having received FORCE's Conditions and irrespective of such general terms and conditions have been expressly rejected by FORCE. In the event of a conflict between the Agreement, these Conditions and/or the specifications, drawings, illustrations and photos the documents prevail in the above-mentioned order.

2. AGREEMENT

2.1 Prior to commencing Services (as defined below) and/or deliveries ("Report"), an agreement shall be concluded in writing between the Parties stating as a minimum the type of work, scope, time schedule, pricing (including whether fixed or time spent) and payment terms.

2.2 Quotations given by FORCE are valid for 30 days unless otherwise agreed in writing.

2.3 Test, calibration and/or product approval, including calibration of product and technical approval constitutes a test, measurement, and/or control of a condition, at any given time within specified standards, framework or by agreement ("Services"). Consultancy services are not part of the scope, unless otherwise stated in the agreement between FORCE and the Customer cf. 3.1.

2.4 FORCE is only liable towards the Customer for test, calibration or product approval performed, unless otherwise directly agreed with FORCE.

2.5 All tests are performed according to existing or agreed standards.

3. CONSULTANCY SERVICE

3.1 In the event that Service by FORCE includes consultancy service, the scope and content of such consultancy service must be specifically agreed between the Parties in writing.

4. FORCE MAJEURE

4.1 Any delay or failure of FORCE to perform its obligations according to the Agreement will be excused if and to the extent that it was caused by an event or occurrence beyond FORCE's reasonable control and without its fault or negligence ("Force Majeure"). Force Majeure includes, but is not limited to, acts of God, actions by any government authority (whether valid or invalid), fires, floods, windstorms, explosions, riots, natural disasters, wars, sabotage, acts of terrorism, or court injunction or order, labour problems of FORCE, or its critical subcontractors, such as, lockouts, strikes, and slowdowns. Further, Force Majeure shall include epidemics, quarantines, isolations and denied access by national authorities to the site of the Customer or work site due to health risks, including restrictions in flights and/or other kind of transportation for the same reason.

4.2 Should a Force Majeure event continue for more than three (3) months, either Party shall have the right to terminate any relevant orders. In case the Customer terminates the Agreement or any order due to Force Majeure, the Customer must pay any outstanding fees or costs including pro rata payment of work performed until the date of notice of termination including unavoidable termination costs of sub-suppliers.

5. WORK ENVIRONMENT AND SAFETY

5.1 The Customer shall ensure safe working conditions and proper instruction to FORCE's personnel when or if entering and working on a site designated by the Customer.

5.2 FORCE's personnel shall have the right without incurring any liability on FORCE or itself to terminate work for the Customer at any time if the FORCE personnel, at their discretion, find that the performance of work at site pose a risk to the FORCE personnel's safety and health or in any other way prevents the safe performance of the work.

6. PRICE

6.1 FORCE reserves the right to modify hourly rates as of January 1st each year. Furthermore, modification of hourly rates can be made with thirty (30) days' notice.

6.2 Materials spent, purchased resources and services for the work are calculated at the agreed rates, or in case of no agreement on this, at FORCE's cost price, with a handling fee of ten percent (10 %).

6.3 FORCE notifies the Customer as soon as it is established that an estimated price of the agreed work materially is higher than the given estimated price, and quotes at

the same time the new price. The Customer is not notified if an estimate increases to less than ten thousand (10,000) DKK or less than twenty percent (20 %) of the most recent estimated price.

6.4 All prices are exclusive of VAT and other taxes.

7. PAYMENT TERMS

7.1 The Customer shall comply with the payment obligations set out in the Agreement.

7.2 In the absence of payment obligations in the Agreement:

a) The Customer shall submit payment to FORCE within thirty (30) days from the date of invoice.
b) Payment shall be made to the bank account specified by FORCE.
c) The Customer shall pay all amounts due under the Agreement in full and without any setoff, counterclaim, deduction or withholding, except if said setoff, counterclaim etc. is required by law and the Customer has documented such request.
d) If a payment is delayed, the Customer shall pay to FORCE an interest rate of one percent (1 %) per month for the duration of the delay.

7.3 If the Customer does not comply with the payment obligations set out in the Agreement or hereunder, FORCE may suspend its performance until the Customer complies with the payment obligations.

7.4 Nothing under this Clause 7 will limit any other right or remedy available to FORCE.

7.5 FORCE reserves the right to set-off against any payments due under the Agreement and/or any other agreement with the Customer.

8. INVOICING

8.1 Unless otherwise agreed upon in writing or stipulated in FORCE's quotation, the Customer may be invoiced, upon acceptance of an order, an advance payment of twenty five percent (25 %) of the fixed or estimated price, however, at least five thousand (5,000) DKK if the price exceeds five thousand (5,000) DKK.

8.2 Ongoing Services including expenses will be invoiced continuously.

8.3 For Services with a fixed price with a duration exceeding thirty (30) days, FORCE may continuously charge on account payments based on FORCE's estimate on pro rata completion.

8.4 Final invoicing will take place at completion of the work.

9. ITEMS TO TEST

9.1 In connection with performance of certain tests it may be necessary to modify the test subject. The test subject may be damaged during testing. FORCE does not undertake that any subject tested can be used for its purpose after the testing.

9.2 After the Service is completed FORCE will return the test subject received from the Customer unless otherwise agreed in writing.

9.3 The shipment return is EXW (INCOTERMS 2020). If the Customer does not facilitate the return of the test subject within thirty (30) days after written notice from FORCE, FORCE is permitted to dispose of the Customers test subject. Any expenses related thereto will be invoiced to the Customer.

9.4 In connection with authority approval of products it can be a requirement for FORCE to store the test subject and any test documentation in a certain period.

10. WARRANTIES

10.1 FORCE undertakes to remedy defects in the Service due to the fault of FORCE.

10.2 The Customer has a standard duty to investigate the work at delivery according to agreement. FORCE's liability for errors and deficiencies shall be limited to errors and deficiencies present on delivery and which become known within twenty-four (24) months from delivery.

10.3 In the event of a claim, the Customer must immediately provide FORCE with a written notice detailing the deficiency or error. Upon receipt of a claim for which FORCE is liable, FORCE will as the only remedy perform a new test, calibration or product approval as relevant, including, if applicable, adjusting the Report.

10.4 FORCE's period of liability for replaced or repaired Service is identical with the period of liability for the original delivered work, which means the new period of liability starts at the same point in time as for the original delivered work.

11. LIABILITY

11.1 FORCE shall not be liable for any costs, loss or damage unless it can be documented and has occurred due to negligence of FORCE in connection with the performance of the Service or deliveries under the Agreement.

11.2 FORCE shall not be liable for loss of operation, loss of time, loss of profits or similar indirect or consequential losses, including any indirect losses which may be remunerated to third parties.

11.3 FORCE performs the requested Service and presents Reports and guidance on the basis of knowledge and engineering available to FORCE at the time of completing the Service.

11.4 FORCE is not liable for damages, costs or loss that may occur in connection with any use of data and results outside of the agreed Service and outside the purpose for which FORCE's Service or Report is issued.

11.5 FORCE is not liable in relation to statements nor estimates, where it is apparent that such are based on discretionary assessments, unless it can be proven that this assessment was clearly incomplete based on the common knowledge or techniques within the industry at the time of completing the Service.

11.6 FORCE is not liable for any loss or damage incurred if the loss or damage is caused by properties or content

of a product or use of a product that has either not been tested nor investigated and described in the Report, or which deviates from FORCE's description in the Report of a product feature or of a possible use of the product.

11.7 FORCE is not liable for any damages incurred, so long as a harmful product or product type has not been actually tested, calibrated or product approved by FORCE, unless the Customer demonstrates a basis for liability and that the damaging product is identical to one that FORCE has specifically tested, calibrated or product approved.

11.8 Notwithstanding any other provisions of the Agreement or related documents, FORCE's total liability, for whatever reason, both in contract and tort, is maximized to the minimum amount of either; the total payment from Customer to FORCE under the specific purchase order under this Agreement or 5,000,000 (five million) DKK. The limitation of liability includes amounts that may be remunerated to third parties.

11.9 In the event of a third-party claim, which FORCE is not liable for under these Conditions, the Customer shall indemnify and hold harmless FORCE for all costs, including legal costs and compensations.

12. MARKETING AND REFERENCE

12.1 In case the Customer wishes to use results from the Service for marketing purposes all references to Services, shall be made to the complete documentation (Report) or product type from FORCE in adherence to applicable law. Any wording in such marketing material is the sole responsibility of the Customer.

12.2 In the event that the Service is ceased or suspended by the Customer in accordance with clause 16.1, the Customer may only use FORCE's name and logo in connection with the Service or its result after written agreement.

13. INTELLECTUAL PROPERTY

13.1 Subject to clause 12 the Customer has full title to Reports, when delivered to the Customer. FORCE's Reports may only be published in their entirety, and with source credits. Use of extracts and in citations is only allowed with written consent.

13.2 FORCE maintains all rights to know-how, technology, methods, trade secrets, design, source code, Software, interfaces, images, graphics, documentation, tools, processes, patents and other intellectual property rights, and reserves the right to all developments, improvements or modifications thereof, including those used or incurred in connection with the performance of the work (collectively "FORCE Rights").

13.3 FORCE retains all rights to data generated by FORCE based on the FORCE Rights regardless of how such arise, and any statistics, information, and other analysis derived from such. FORCE shall have royalty free, perpetual, right to use and further improve or develop for any of its products or services or FORCE Rights including machine learning of any data that may belong to the Customer (and of which inferred statistics, information and other analysis) arising from access to or use of the FORCE Rights by, or on behalf of, the Customer, regardless of how such have occurred, while respecting confidentiality, cf. clause 14.

13.4 The Customer must respect the obligations of FORCE under the Danish Employee's Inventions Act.

14. INFORMATION AND CONFIDENTIALITY

14.1 FORCE treats Customer information, the performance of Services, and other details in relation to the customer relationship confidentially. However, FORCE may use the Customer's name and the overall scope of the Service for reference unless the Customer relationship itself is subject to a separate confidentiality agreement.

14.2 FORCE being a GTS institute, means that FORCE is subject to Ministerial supervision, which includes user surveys of Danish Customers, and in this regard, FORCE shall provide Customer's company name, VAT number and address unless the Customer relationship itself is subject to a separate confidentiality agreement.

15. CUSTOMERS CANCELLATION OR POSTPONEMENT OF THE WORK BEFORE START

15.1 The Customer can cancel or postpone the work until thirty (30) days before the agreed start of the Service.

15.2 If the Service is cancelled or postponed thirty (30) days or less before the agreed start, the Customer will be invoiced a cancellation- or postponement fee of twenty percent (20 %) of the price for the work or the estimated price of the work, however not less than five thousand (5,000) DKK and maximum one hundred thousand (100.000) DKK. This will also apply if the Customer is responsible for delays in the work.

16. THE RIGHT OF THE CUSTOMER TO STOP THE WORK

16.1 Should the Customer wish to cease the Service, the Customer must pay for Services already performed, with the addition of the costs incurred by FORCE for staff, equipment etc. as a consequence of the Service being ceased.

16.2 Notwithstanding the above, the Customer's total payment shall never exceed the agreed or estimated price for the Service, and never be less than twenty percent (20 %) of the estimated or fixed price, however, no less than five thousand (5,000) DKK.

16.3 After the Service has ceased the Customer will receive any preliminary results of the Service in the form available at the cessation time.

16.4 If the Service is stopped at the request of the Customer, (i) FORCE's liability for errors and deficiencies in performed work will lapse and, (ii) any subsequent use

of the results received is the sole responsibility of the Customer.

17. TERMINATION

17.1 The Agreement may be terminated by either Party with thirty (30) days written notice, however, the Customer must pay any outstanding fees or costs including pro rata payment of work performed until the date of notice of termination including unavoidable termination costs of sub-suppliers.

17.2 In case of material breach of the Agreement and/or these Conditions FORCE may terminate without notice. Any breach of clauses 18 and 19 is a considered a material breach.

18. BUSINESS ETHICS AND CODE OF CONDUCT

18.1 FORCE's Code of Conduct applies to FORCE and any performance by the Parties under this Agreement.

19. SANCTIONS AND EXPORT CONTROL

19.1 Customer represents and warrants that it is not subject to any sanctions, including but not limited to sanctions issued by the United States Department of Treasury Office of Foreign Assets Controls (OFAC), the European Union, or any other applicable sanctions rules ("Sanctions") that would prevent FORCE from transacting business with the Customer, and agrees that it shall comply with such Sanctions.

19.2 In the event that the Customer, or its affiliates, is or becomes subject to Sanctions at any point in time, FORCE shall have the right to amend the Agreement, withhold any deliverables and payments, and reject payments in order to comply with the applicable Sanctions.

19.3 If, as a part of the Service performed under the Agreement, the Customer shall deliver or disclose to FORCE any technologies, products, test objects or elements that are covered by any global export control programmes such as the European Union Regulation (EC) No 428/2009 or similar, the Customer represents and warrants that the delivery and redelivery of the product, test object, or Report has received relevant export control approval from the applicable authorities. Failure to ensure that items and other elements that are covered by export control regulations have received adequate approvals will cause Customer to be liable and Customer shall indemnify FORCE for any losses, damages or costs in respect of such non-compliance.

20. GOVERNING LAW AND DISPUTES

20.1 The Agreement, including these Conditions are governed by Danish law, without giving effect to its provision or rules regarding conflicts of law.

20.2 Any dispute arising between the Parties including disputes arising out of the performance of the Service or the interpretation of the Agreement and/or these Conditions shall, if such dispute cannot be solved amicably between the Parties within reasonable time, be settled by the Danish Arbitration Institute in accordance with the rules of arbitration procedure adopted by The Danish Institute of Arbitration and in force at the time when such proceedings are commenced. The process shall be subject to strict confidentiality.

21. ACCREDITED SERVICES

21.1 Accredited services are performed subject to applicable regulations on accreditation, as amended from time to time, and in accordance with and limited in scope to the relevant standards.

21.2 FORCE is subject to the supervision of the accreditation authority, which has a duty of confidentiality. The Customer agrees that FORCE, for accredited services, provides the accreditation authority access to the Customer's information for the execution of review and audits.

Test Report 3219724.

Guangxi Anran Medical Equipment Co., Ltd.

Introduction.

This report has been prepared by Ben Hobbs and relates to the activity detailed below:

Job/Registration Details		Client Details
Job number:	**3219724**	Guangxi Anran Medical Equipment Co., Ltd.
Job type:	Testing Samples Submitted	Room 3-1, No. 3, Workshop
Start Date:	06/06/2020	No. 1, Yinxiang Road
Test type:	Type	Liunan District
Sample ID:	10190166	Liuzhou City
Registration:	**CE 730096**	Guangxi
Scheme:	Negative pressure RPE	545000
Protocol:	PP123	China
Scheme Manager:	Nathan Shipley	

The report has been approved for issue by T Wicksey – Senior Test Engineer

Approved For Issue	
	Issue Date: 6 July 2020

Objectives.

This is an independent test evaluation to only certain clauses or sub-clauses of the agreed specification in accordance with the following test programme:

BSI COVID-19 filtering face piece technical specification, for COVID-19 masks for use by healthcare workers

Product Scope.

COVID-19 masks for use by healthcare workers

Report Summary.

The samples were received on 3 June 2020 and the testing was started on 6 June 2020.

The samples submitted complied with the requirements of the test work conducted.

Test Samples.

Sample ID	ER Number	Description
1 to 19	10190166	Model: AN RAN 9501A

Description of Test Samples.

Sample Description
COVID-19 masks for use by healthcare workers: Model: AN RAN 9501A

Test Requirements.

Testing in accordance with BSI COVID-19 filtering face piece technical specification
Technical testing specification for COVID-19 masks for use by healthcare workers

EN 149:2001+A1:2009 Performance requirement	EN 149:2001+A1:2009 Test method clause	Requirement	Assessment
7.7 Practical performance The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. *2 test subjects, masks tested 'As received'*	Testing shall be done in accordance with 8.4.	During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded: a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.	Pass
7.9 Leakage **7.9.1 Total inward leakage** *5 test subjects, masks tested 'As received'*	Testing shall be done in accordance with 8.5.	All samples must achieve All individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2)	Pass
7.9 Leakage **7.9.2 Penetration of filter material** *3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3min test*	Testing shall be done in accordance with 8.11	6% for both PO and NaCl	Pass
7.12 Carbon dioxide content of the inhalation air *3 test samples, masks tested 'As received'*	Testing shall be done in accordance with 8.7.	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	Pass
7.16 Breathing resistance *3 test samples, masks tested 'As received'*	Testing shall be done in accordance with 8.9	The breathing resistances shall meet the requirements of; 30l/min – 0.7mbar (inhale) 95l/min – 2.4mbar (inhale) 160l/min – 3.0mbar (exhale)	Pass
Appendix A - Test Panel Data			
Product Photographs			

Glossary of Terms.

Pass: Complies. Tested by BSI engineers at BSI laboratories
Pass 1: Complies. Witnessed by BSI engineers in manufacturers laboratory.
Pass 2: Complies. Tests carried out by third party lab; results accepted by BSI.
Pass*: Report resulted in uncertainty and states that Compliance is more probable than non-compliance.
Fail: Non-compliance. Product does not meet the requirements of this clause.
Fail*: Report resulted in uncertainty and states that Non-compliance is more probable than compliance.
N/T: Not Tested
N/A: Not Applicable
AR: As Received
TC: Temperature Conditioned
SW: Simulated Wear
FT: Flow Tested
MS: Mechanical strength
MMDF: Manufactures Minimum Design Flow
MMDC: Manufactures Minimum Design Condition

Conditions of Issue.

This Test Report is issued subject to the conditions stated in current issue of 'BSI Terms of Service'. The results contained herein apply only to the particular sample(s) tested and to the specific tests carried out, as detailed in this Test Report. The issuing of this Test Report does not indicate any measure of Approval, Certification, Supervision, Control or Surveillance by BSI of any product. No extract, abridgement or abstraction from a Test Report may be published or used to advertise a product without the written consent of BSI, who reserve the absolute right to agree or reject all or any of the details of any items or publicity for which consent may be sought.

Should you wish to speak with BSI in relation to this report, please contact Customer Services on +44 (0)8450 80 9000.

BSI
Kitemark House
Maylands Avenue
Hemel Hempstead
Hertfordshire
HP2 4SQ

UKAS TESTING
0135

Opinions and Interpretations expressed herein are outside the scope of our UKAS accreditation.
Unless otherwise stated, any results not obtained from testing in a BSI laboratory are outside the scope of our UKAS accreditation.

Test Results.

Testing in accordance with BSI COVID-19 filtering face piece technical specification

BS EN 149:2001 +A1:2009 Technical testing specification for COVID-19 masks for use by healthcare workers

CLAUSE	REQUIREMENTS	ASSESSMENT
7.7	**Practical performance** The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. Test in accordance with clause 8.4 of the standard.	Pass
	Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers *During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded:* *a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.*	

Table A: Practical performance

Test candidate	Sample	Comments				Assessment
		Head harness comfort	Security of fastenings	Field of vision	Any other comments	
MM2	1 AR	OK	OK	OK	None	Pass
JW1	2 AR	OK	OK	OK	None	Pass

7.9 Leakage

7.9.1 Total inward leakage

The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected.

The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration.

Test in accordance with clause 8.5 of the standard. Pass

Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers

5 test subjects, masks tested 'As received'. All individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2).

Table B: Clause 7.9.1 - Total inward leakage

Test candidate	Sample	Pre test condition	Inward Leakage (%)						Assessment
			A	B	C	D	E		
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking	Average	
JW1	3	AR	1.6120	2.1789	1.2090	1.3280	3.2189	1.9094	Pass
RF1	4	AR	2.1172	3.1556	6.5921	1.7040	2.8246	3.2787	Pass
BH2	5	AR	0.2503	0.6014	3.3718	4.0296	9.1903	3.4887	Pass
LM2	6	AR	0.1036	0.2034	2.5496	0.2689	0.1635	0.6578	Pass
MM2	7	AR	0.2202	0.4215	0.6548	0.7861	0.8227	0.5811	Pass

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.9.2	Penetration of filter material ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3 min test. Testing shall be done in accordance with 8.11. 6% limit for both PO and NaCl*	Pass

Table C: Clause 8.11 - Sodium Chloride penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
8	AR	95	< 6	0.1023
9	AR			0.0771
10	AR			0.0955

Table D: Clause 8.11 - Paraffin oil penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
11	AR	95	< 6	0.3180
12	AR			0.9170
13	AR			0.3245

7.12 Carbon dioxide content of inhalation air

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

Test in accordance with clause 8.7 of the standard.

Table E: Clause 8.7 - Carbon Dioxide content of the inhalation air

Sample	Pre-test condition	Dead space CO_2 (%)	
		Limit	Measured
14	AR	< 1.0	0.50
15	AR		0.55
16	AR		0.55

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.16	**Breathing resistance** ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *3 test samples masks tested 'As received'. Test in accordance with clause 8.9 of the standard.* *The breathing resistances shall meet the requirements of FFP2;* *30l/min – 0.7mbar (inhale), 95l/min – 2.4mbar (inhale), 160l/min – 3.0mbar (exhale)*	Pass

Table F: Clause 8.9 – Breathing resistance. Inhalation resistance at a continuous flow

Sample	Pre-test condition	Continuous flow (l/min)	Inhalation resistance (mbar)	
			Limit	Measured
17	AR	30	< 0.7	0.33
18	AR			0.28
19	AR			0.28
17	AR	95	< 2.4	0.96
18	AR			0.91
19	AR			0.92

Table G: Clause 8.9 – Breathing resistance. Exhalation resistance at a continuous flow, measured in five orientations with the worst case reported

Sample	Pre-test condition	Continuous flow (l/min)	Exhalation resistance (mbar)	
			Limit	Measured
17	AR	160	< 3.0	1.52
18	AR			1.45
19	AR			1.46

Appendix A. – Test Panel Data

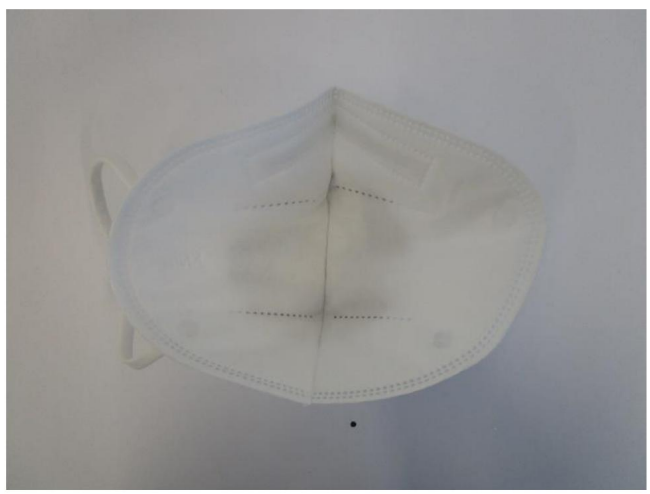
Test Candidate	Facial Dimensions (mm)					Sex
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
MM2	119	150	115	53	595	Male
JW1	116	126	122	48	570	Male
RF1	104	122	121	55	549	Male
BH2	124	148	120	51	595	Male
LM2	110	148	125	47	567	Male

Note: All candidates were clean shaven

Product photographs.

Front view

Side View



Inside View

End of Report