EXHIBIT 8

From: John Thomas
Sent: Tuesday, March 24, 2020 9:30 AM PDT
To: Wong, Michael@DGS
BCC: Browning, Abby@CalOES; Mike Gula; Jennilee Brown
Subject: Re: Medical Supplies Sheet
Attachments: N95-Foldable.zip, GZ Harley (1).zip, Wondfo SARS-CoV-2 Antibody test (lateral flow method).zip

Dear Michael,

Is this what you mean for specs? Please see attached.

Can you provide me with a rough estimate of much and by when you need it I can start shuffling around things on my end now to make sure we can get you what you need?

Thanks!

John

On Mon, Mar 23, 2020 at 9:43 PM John Thomas <john@blueflame.agency> wrote:

> Thanks, Michael. Yes I have all the spec sheets I'll package up.
>
> We can do a 75% prepayment and the balance upon receipt. I have to give them pre-payment but you have the 48 hour inspection period or you can reject the goods and you get a refund. Also I just got word from my lead manufacturer that we need to place an order for 100mil n95 masks or they will sell them to the UK. I HIGHLY suggest we lock them in now. We can have you place a deposit on the 100mil mask order to make sure the inventory doesn't disappear and then do the usual 75% prepayment per lot that gets shipped over time.
>
> I'm happy to show you the text messages back and forth to this manufacturer. We literally have 9 hours to make this call on the masks. I strongly encourage that you move on this one.
>
> Thanks again. As always i'm available 24/7.
>
> John
>
> On Mon, Mar 23, 2020 at 6:52 PM Wong, Michael@DGS <Michael.Wong@dgs.ca.gov> wrote:
>
> > John, do you have specification sheets for the N95 masks and the COVID19 test kits?
> >
> > Also, what other options do we have for payment to foreign manufacturers?
> >
> > Respectfully,

Michael Wong

Contracts Administrator

Phone: 916-441-9619

Email: Michael.Wong@dgs.ca.gov

From: John Thomas [mailto:john@blueflame.agency]
Sent: Monday, March 23, 2020 6:38 PM
To: Wong, Michael@DGS <Michael.Wong@dgs.ca.gov>
Subject: Medical Supplies Sheet

Dear Michael,

Pleasure texting with you. Here's our sales sheet for today. I have some inventory in california, some in Mexico and a huge global supply chain that can service any need you have going forward.

Hand sanitizer I just came into a bunch of inventory of hand sanitizer based here in Riverside, California that is 80% alcohol levels. Also we can make children's n95 masks now at about 9 mil units a month. This isn't on the sales sheet.

75,000 6oz units that we can private label.

1 mil bottles of 2oz hand sanitizer.

If you want I can have this moved to you tomorrow.

Please let me know what the next steps are.

Thanks again!

John

--

John Thomas

President

Blueflame Strategies

c. (818) 636-6522

e. john@blueflame.agency

--
John Thomas
President
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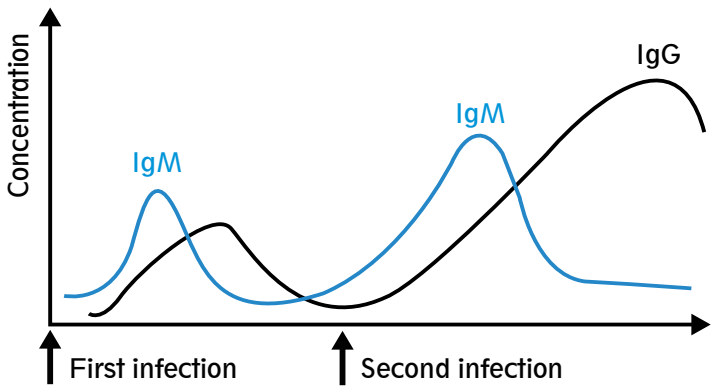
Wondfo®

SARS-CoV-2 Antibody Test

(Lateral flow method)

- As an auxiliary and supplementary method for the further diagnosis to the patients with negative result in PCR.
- Easy to use, instant result in 15 minutes

According to the Novel Coronavirus Pneumonia Diagnosis and Treatment Plan (7th Edition) published by general office of national health committe, serology testing can be used as a diagnostic method of COVID-19 infection.



Antibodies can be detected as early as one week after infection, with slightly difference between individuals.

1. Negative result indicates no infection or infection at a very early stage (within first few days).
2. Positive result indicates an infection with coronavirus.

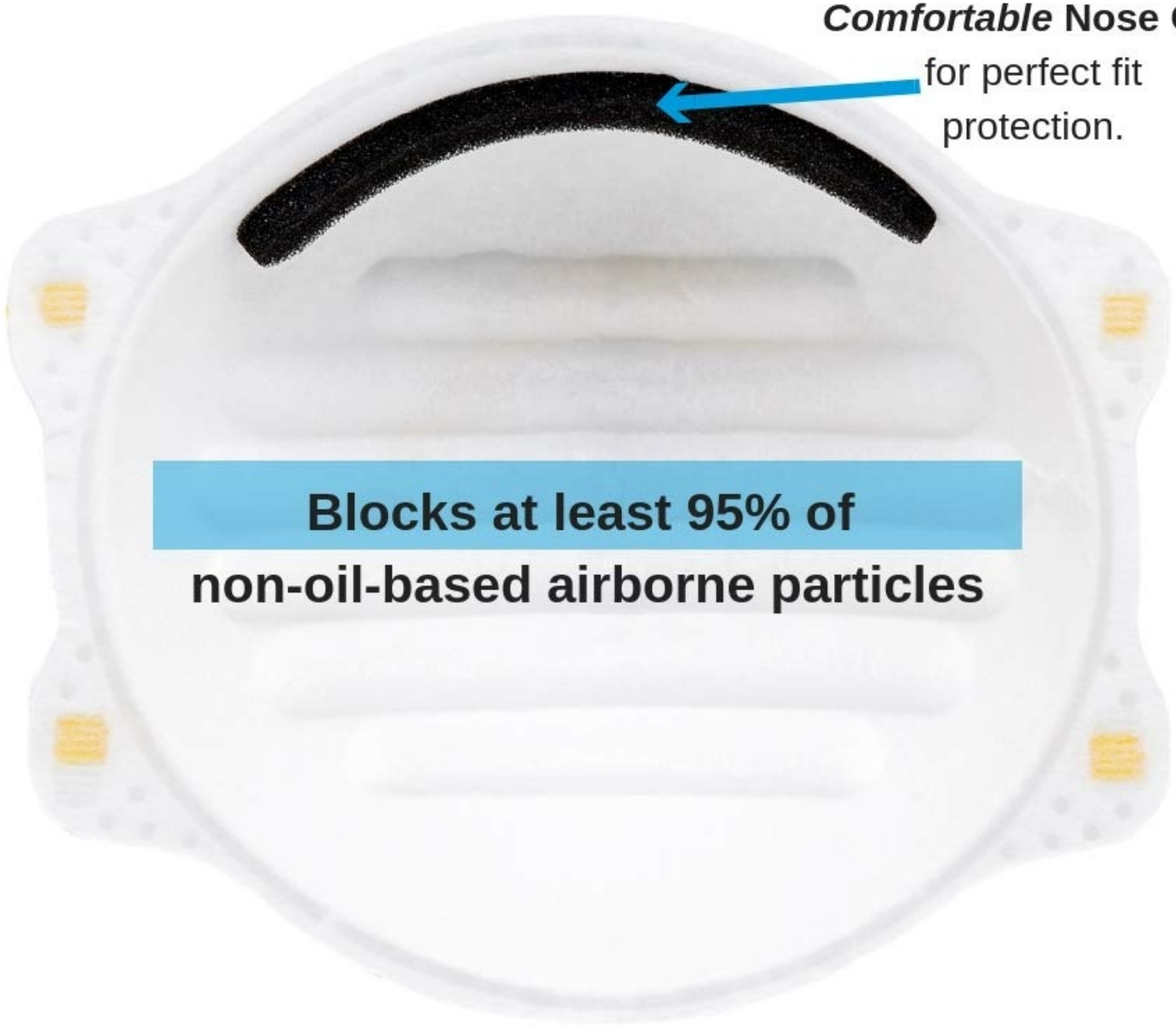
Order information

Product name	Packing size	Sample type	Storage condition	Shelf life
SARS-CoV-2Antibody Test (Lateral flow method)	20T	Whole blood, serum and plasma	2℃~30℃	6 months

Wondfo®
Guangzhou Wondfo Biotech Co., Ltd.
Add: No. 8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China
Websites: en.wondfo.com.cn


N95
NIOSH N95
DTC3B
TC-84A-4336

National Institute for Occupational Safety and Health
NIOSH®



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

NIOSH Reference: TN-19168
Mfr. Reference: MAK-1310

October 17, 2013

Mr. Alexander Freedman, President
Makrite Industries Inc.
Sanax Protective Products, Inc.
105 Palmer River Road
Swansea, MA 02777

Dear Mr. Freedman:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted May 29, 2013. This request was for an approval of the model SEKURA-321 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference the assembly matrix SEKURA-321AMa.xls.

This request is granted. Approval is granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. The approval number TC-84A-6660 has been assigned. This respirator is approved for protections against particulates at a N95 filter efficiency level.

The CD enclosed with this letter contains the final respirator label. The abbreviated label has been accepted as submitted. The cautions and limitations that apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval labels in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that the respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely yours,

Roland BerryAnn
Acting Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Technology Evaluation Branch
Certification, Evaluation and Testing Section
P.O. Box 18070
Pittsburgh, PA 15236

TEST REPORT

Task Number: TN-19168

Manufacturer: Makrite Industries, Inc.

Prepared by: Jeremy Brannen

Tests Conducted by: Jeremy Brannen / Nicole Petitta

Date: July 30, 2013

Respirator Tested: SEKURA-321

Background Information

In an application accepted May 29, 2013 Makrite Industries requested an approval of the model SEKURA-321 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference the assembly matrix SEKURA-321AMa.xls.

Tests Assigned

Test Description	STP Number	Reference
A. Exhalation Resistance Test	RCT-APR-STP-0003	84.180
B. Inhalation Resistance Test	TEB-APR-STP-0007	84.180
C. Sodium Chloride (NACL) N95 Test	TEB-APR-STP-0059	84.181

Overall Results

The items tested passed laboratory testing.

Individual Test Results

See the attached test data sheets.

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-19168 **Reference No.:** CFR 84.180
Test: Exhalation Resistance Test **STP No.:** 3
Manufacturer: Makrite Industries, Inc.

Filter Type: Filter Only

Item Tested: SEKURA-321

Sample	Maximum Allowable Resistance (MM of H2O) Exhalation	Actual Resistance (MM of H2O) Exhalation	Result
1	25	10.4	PASS
2	25	10.9	PASS
3	25	8.9	PASS

Overall Result: PASS

Comments:

Was all equipment verified to be in calibration throughout all testing? (•) Yes ( ) No

Signature: Nicole L. Petitta **Date:** 7/30/2013

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-19168
Test: Inhalation Resistance Test
Manufacturer: Makrite Industries, Inc.
Item Tested: SEKURA-321

Reference No.: CFR 84.180
STP No.: 7

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O) Inhalation	Actual Resistance (MM of H2O) Inhalation	Result
1	35	13.7	PASS
2	35	11.4	PASS
3	35	10.2	PASS

Overall Result: PASS

Signature: Nicole L. Petitta **Date:** 7/30/2013

Engineering Technician

Task Number: TN-19168
Test: Inhalation Resistance Test
Manufacturer: Makrite Industries, Inc.
Item Tested: SEKURA-321

Reference No.: CFR 84.180
STP No.: 7

Comments:

Was all equipment verified to be in calibration throughout all testing? ◉ **Yes** ○ **No**

Signature: Nicole L. Petitta **Date:** 7/30/2013

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-19168 **Reference No.:** CFR 84.181
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer: Makrite Industries, Inc.
Item Tested: SEKURA-321

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	13.4	5.00	1.310	1.310	PASS
2	85	13.8	5.00	1.170	1.360	PASS
3	85	11.6	5.00	0.578	0.588	PASS
4	85	15.3	5.00	0.800	0.851	PASS
5	85	13.2	5.00	0.601	0.611	PASS
6	85	13.2	5.00	0.634	0.647	PASS
7	85	12.9	5.00	0.649	0.659	PASS
8	85	15.5	5.00	0.572	0.572	PASS
9	85	11.2	5.00	0.298	0.317	PASS
10	85	13.8	5.00	0.922	0.922	PASS
11	85	14.7	5.00	0.857	0.857	PASS
12	85	11.0	5.00	0.395	0.436	PASS
13	85	11.3	5.00	0.353	0.384	PASS
14	85	13.2	5.00	0.454	0.483	PASS
15	85	14.5	5.00	0.881	0.881	PASS
16	85	13.1	5.00	0.790	0.790	PASS
17	85	10.0	5.00	0.556	0.556	PASS
18	85	14.7	5.00	0.886	0.886	PASS
19	85	11.6	5.00	0.651	0.651	PASS
20	85	15.6	5.00	1.100	1.100	PASS

Overall Result: PASS

Signature: 
Date: 7/30/2013

Engineering Technician

Task Number: TN-19168 **Reference No.:** CFR 84.181
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer: Makrite Industries, Inc.
Item Tested: SEKURA-321

Comments:

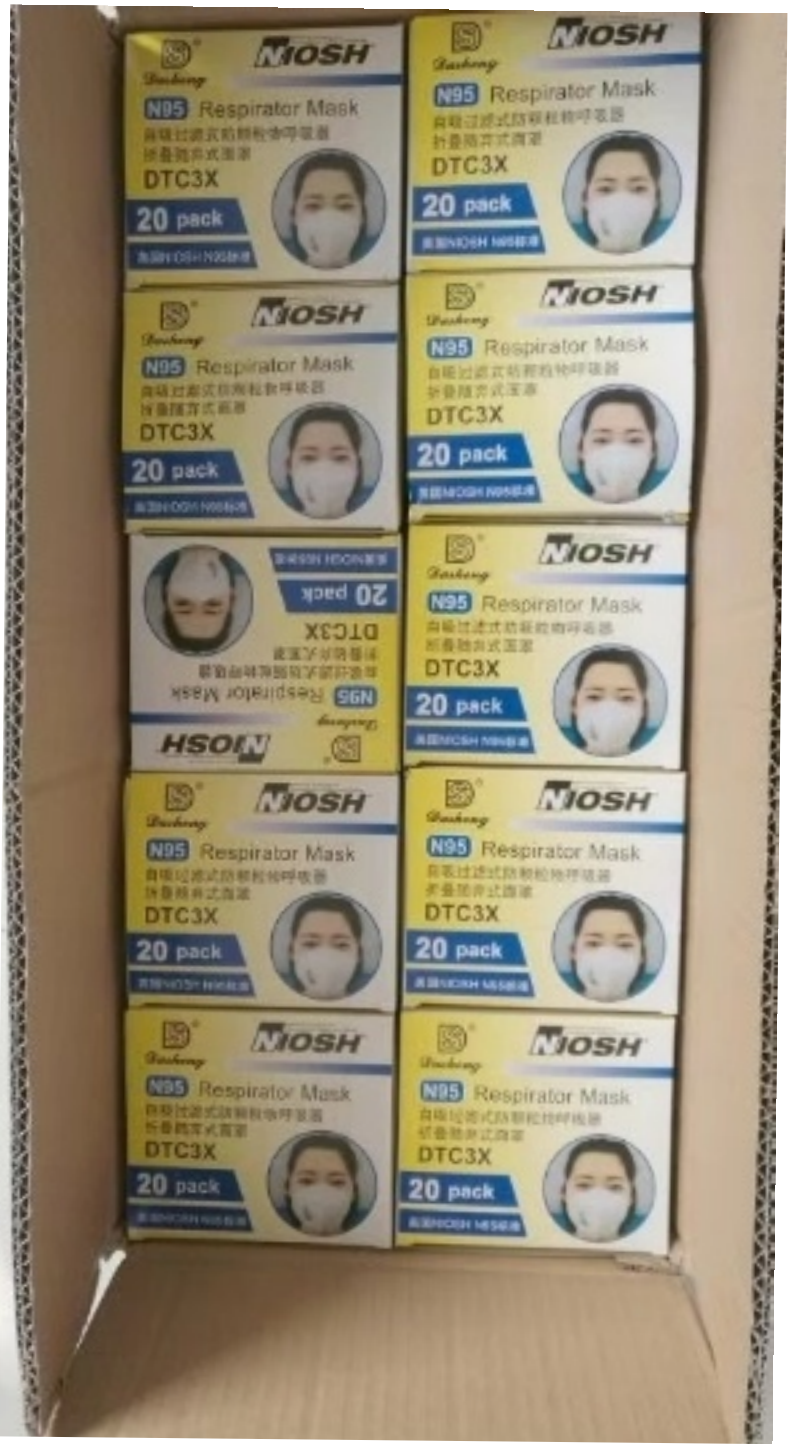
Was all equipment verified to be in calibration throughout all testing? ◉ Yes ○ No

Signature:  **Date:** 7/30/2013

Engineering Technician


MAKRITE SEKURA-321
TC-84A-6660
MIOSH N95


DTC3X
TC-84A-4329
NIOSH N95
N95



Wondfo®

SARS-CoV-2 Antibody Test (Lateral Flow Method)

Catalog No.: W195

INTENDED USE

Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) is an immunochromatographic assay for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgG/IgM antibody in human whole blood, serum or plasma sample. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2.

The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision.

For in vitro diagnostic use only. For professional use only.

SUMMARY

On December 31, 2019, several cases of pneumonia in Wuhan City, Hubei Province of China were reported to the World Health Organization (WHO). The novel virus, now known as SARS-CoV-2 (previously known as 2019-nCoV), a RNA virus of the beta coronavirus family, has since spread across China and to other countries and territories. The WHO has named the disease caused by SARS-CoV-2 as coronavirus disease 2019 (abbreviated "COVID-19").

PRINCIPLE

Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) is based on the principle of capture immunoassay for determination of SARS-CoV-2 IgG/IgM antibodies in human whole blood, serum and plasma. When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the SARS-CoV-2 antigen-dye conjugate and flows across the pre-coated membrane.

When the SARS-CoV-2 antibodies level in the specimen is at or above the target cutoff (the detection limit of the test), the antibodies bound to the antigen-dye conjugate are captured by anti-human IgG antibody and anti-human μ chain antibody immobilized in the Test Region (T) of the device, and this produces a colored test band that indicates a positive result. When the SARS-CoV-2 antibody level in the specimen is zero or below the target cutoff, there is not a visible colored band in the Test Region (T) of the device. This indicates a negative result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

PRECAUTION

1. This kit is for *in vitro* diagnostic use only.
2. All specimens should be treated as capable of transmitting diseases. Use appropriate precautions in the collection, handling, storage and disposal of patient samples and used kit contents. And follow biosafety level 2 or higher guidelines.
3. Wear appropriate personal protective equipment (e.g. gowns, gloves, eye protection) when handing the contents of this kit.
4. Proper specimen collection storage and transport are critical to the performance of this test.
5. Discard after first use. The test cannot be used more than once.
6. Do not touch the reaction area of test strip.
7. Do not use test kit beyond the expiration date.
8. Do not use the kit if the pouch is punctured or not well sealed.
9. Testing should be applied by professionally trained staff working in certified laboratories or clinics at which the sample(s) is taken by qualified medical personnel.
10. The test result should be interpreted by the physician along with clinical findings and other laboratory test results.
11. DISPOSAL OF THE DIAGNOSTIC: All specimens and the used-kit has the infectious risk. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory regulation.

MATERIAL

Material Provided

1. 20 Individual sealed pouches, each pouch contains:
   - 1 x Test cassette
   - 1 x Desiccant pouch
2. 20 disposable droppers
3. Detection buffer (1*6 mL)
4. Instructions for use

Material Required but Not Provided

1. Specimen Collection Containers
2. Centrifuge (for serum/plasma sample)
3. Timer
4. Personal protective equipment, such a protective gloves, medical mask, goggles and lab coat.
5. Appropriate biohazard waste container and disinfectants.

STORAGE AND STABILITY

1. Store at 2~30ºC in the sealed pouch up to the expiration date printed on the package. Do not freeze.
2. The test cassette should be used within 1 hour after taking out from the foil envelope. Buffer solution should be re-capped in time after use.
3. Keep away from sunlight, moisture and heat.
4. Kit contents are stable until the expiration date printed on the outer box.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with whole blood, serum and plasma.

For whole blood:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (containing EDTA, Heparin or Citrated sodium). Other anticoagulants have not been validated and may give incorrect result.
2. It is recommended that whole blood specimen is tested at the time of specimen collection. If the specimens are not tested immediately, they may be stored at 2ºC～8ºC for up to 7 days. Prior to testing, mix the blood by gentle inversion several times, do not freeze or heat whole blood specimens.

For Serum and Plasma:

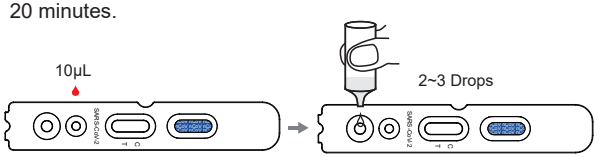
1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (containing EDTA, Heparin or Citrated sodium). Other anticoagulants have not been validated and may give incorrect result.
2. Centrifuge whole blood and separate the plasma from red blood cell as soon as possible to avoid hemolysis.
3. Test should be performed within 8 houres after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum or plasma specimens may be stored at 2ºC～8ºC for up to 3 days prior to testing. Serum or plasma specimens may be stored at -20ºC for up to 9 days.

Note: Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Severe hemolytic or heat-inactivated specimens are not recommended.

TEST PROCEDURE

Please read the instruction for use carefully before performing the test.

1. Allow the device, buffer and specimen to equilibrate to room temperature (10ºC ～30ºC) prior to testing.
2. Remove a test cassette from the foil pouch by tearing at the notch and place it on a level surface.
3. Transfer 10 μL of whole blood or serum or plasma specimen to the sample well (small well) and then add 2-3 drops (80 μL) of buffer solution to the buffer well (large well).
4. As the test begins to work, you will see purple color move across the result window in the center of the test device.
5. Wait for 15 minutes and read the results. Do not read results after 20 minutes.



Note: the rightmost window on the cassette shows the product abbreviation "nCoV" to identify this product.

RESULT INTERPRETATION

Positive Result

Colored bands appear at both test line (T) and control line (C). It indicates a positive result for the SARS-CoV-2 antibodies in the specimen.

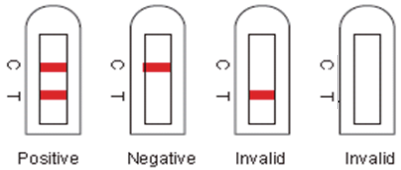
Negative Result

Colored band appear at control line (C) only. It indicates that the concentration of the SARS-CoV-2 antibodies is zero or below the

detection limit of the test.

Invalid Result

No visible colored band appear at control line after performing the test. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

LIMITATIONS OF PROCEDURE

1. This reagent is designed to detect antibodies against SARS-CoV-2 in human whole blood, plasma, serum sample.
2. This reagent is a qualitative assay. It is not designed to determine the quantitative concentration of SARS-CoV-2 antibodies.
3. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, or repeated freezing and thawing of the sample will affect the test result.
4. The test result of this reagent are for clinical reference only, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.
5. Limited by the method of antibody detection reagents, for negative test results, it is recommended to use nucleic acid detection or virus culture identification methods for review and confirmation.
6. Positive test results do not rule out co-infections with other pathogens. A negative result of this reagent can be caused by:
   1) Improper sample collection, improper sample transfer or handing, the virus titer in the sample is too low;
   2) The level of SARS-CoV-2 antibodies is below the detection limit of the test.
   3) Variations in viral genes may cause changes in antibody determinants.

PERFORMANCE CHARACTERISTICS

A. Sensitivity and Specificity

596 clinical case samples which include 361 confirmed case samples* and 235 confirmed excluded case samples*, were obtained for testing, and then compared the test results between Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) and the confirmed case samples. The results of sensitivity and specificity between the two method are show below:

Reagents		Clinical cases		Total
		Confirmed case samples	Excluded case samples	
Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method)	Positive	312	1	313
	Negative	49	234	283
Total		361	235	596

* Confirmed cases were the patients diagnosed according to the treatment plan.
* Confirmed excluded cares were identified by negative PCR results.

Results analysis:
Sensitivity: 86.43% (95%CI: 82.41%~89.58%)
Specificity: 99.57% (95%CI: 97.63%~99.92%)
Total consistent: 91.61% (95%CI: 89.10%~93.58%)

B. Cross-reactivity

Specimens which tested positive with following various agents from patients were investigated with Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method). The results showed no cross reactivity.

Parainfluenza virus antibody
Influenza A antibody
Influenza B antibody
Chlamydia pneumonia antibody
Mycoplasma pneumoniae antibody
Adenovirus antibody
Respiratory syncytial virus antibody
Hepatitis B surface antibody
Hepatitis C virus antibody
Treponema pallidum antibody
HIV antibody
EB virus antibody
Measles virus antibody
Cytomegalovirus antibody
Enterovirus type 71 antibody
Mumps antibody
Varicella-zoster virus positive sample

C. Interferences

The test result of Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) do not be interfered with the substance at the following concentration:

Substance	Concentration
Bilirubin	250 μmol/L
Hemoglobin	9 g/L
Triglyceride	15 mmol/L
Rheumatoid factors	80 IU/mL
Antinuclear antibody (ANA) titer	1:240
Anti-mitochondrial antibody (AMA)	80 U/mL
Mouse IgG	1000 μg/mL

D. Precision

1. Within run precision was determined by using 10 replicates of three different specimens containing different concentrations of antibody. The negative and positive values were correctly identified 100% of the time.
2. Between run precision was determined by using the three different specimens containing different concentrations of antibody in 3 different lots of test devices. Again negative and positive results were correctly identified 100% of the time.

BIBLIOGRAPHY

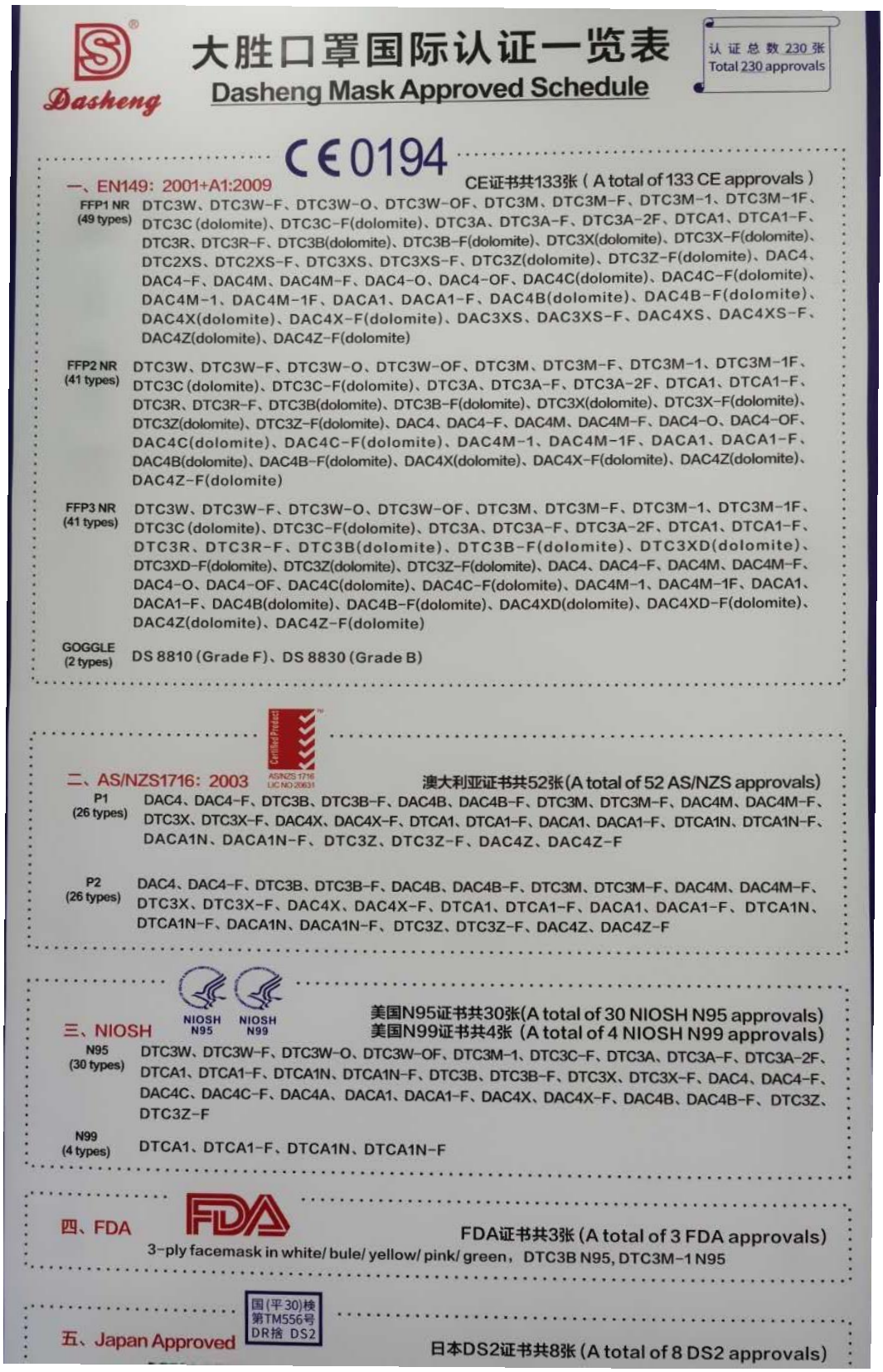
[1] Na Zhu, Ph.D., Dingyu Zhang, M.D., Wenling Wang, Ph.D., et al. (2020). A Novel Coronavirus from Patients with Pneumonia in China, 2019. The New England Journal of Medicine.
[2] Chen Wang, Peter W Horby, Frederick G Hayden, George F Gao. (2020). A novel coronavirus outbreak of global health concern. The Lancet, 395(10223), 470-473.
[3] Chaolin Huang, Yeming, et al. (2020). Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. The Lancet, 395(10223), 497-506.
[4] Nanshan Chen, Min Zhou, Xuan Dong, et al. (2020). Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. The Lancet, 395(10223), 507-513.
[5] World Health Organization: Clinical management of severe acute respiratory infection when Novel coronavirus (nCoV) infection is suspected: Interim Guidance. 12 January, 2020.

INDEX OF SYMBOL

IVD	*In Vitro* Diagnostic Use		See Instruction for Use		Expiry Date
Σ	Tests per Kit		Manufacturing Date		Keep Dry
LOT	Batch Number		Manufacturer		Keep away from Sunlight
30°C 2°C	Store between 2～30°C		Do not reuse	REF	Catalog #

Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R.China
Tel: +86-20-32296083 400-888-5268(Toll Free)
Fax: +86-20-32296063
E-mail: sales@wondfo.com.cn
Website: www.wondfo.com.cn

Rev. A1 Rel.: 2020/02/28



大胜口罩国际认证一览表
Dasheng Mask Approved Schedule

Dasheng

认证总数 230 张
Total 230 approvals

CE0194

一、EN149: 2001+A1:2009

CE证书共133张（A total of 133 CE approvals）

FFP1 NR (49 types) DTC3W、DTC3W-F、DTC3W-O、DTC3W-OF、DTC3M、DTC3M-F、DTC3M-1、DTC3M-1F、DTC3C (dolomite)、DTC3C-F(dolomite)、DTC3A、DTC3A-F、DTC3A-2F、DTCA1、DTCA1-F、DTC3R、DTC3R-F、DTC3B(dolomite)、DTC3B-F(dolomite)、DTC3X(dolomite)、DTC3X-F(dolomite)、DTC2XS、DTC2XS-F、DTC3XS、DTC3XS-F、DTC3Z(dolomite)、DTC3Z-F(dolomite)、DAC4、DAC4-F、DAC4M、DAC4M-F、DAC4-O、DAC4-OF、DAC4C(dolomite)、DAC4C-F(dolomite)、DAC4M-1、DAC4M-1F、DACA1、DACA1-F、DAC4B(dolomite)、DAC4B-F(dolomite)、DAC4X(dolomite)、DAC4X-F(dolomite)、DAC3XS、DAC3XS-F、DAC4XS、DAC4XS-F、DAC4Z(dolomite)、DAC4Z-F(dolomite)

FFP2 NR (41 types) DTC3W、DTC3W-F、DTC3W-O、DTC3W-OF、DTC3M、DTC3M-F、DTC3M-1、DTC3M-1F、DTC3C (dolomite)、DTC3C-F(dolomite)、DTC3A、DTC3A-F、DTC3A-2F、DTCA1、DTCA1-F、DTC3R、DTC3R-F、DTC3B(dolomite)、DTC3B-F(dolomite)、DTC3X(dolomite)、DTC3X-F(dolomite)、DTC3Z(dolomite)、DTC3Z-F(dolomite)、DAC4、DAC4-F、DAC4M、DAC4M-F、DAC4-O、DAC4-OF、DAC4C(dolomite)、DAC4C-F(dolomite)、DAC4M-1、DAC4M-1F、DACA1、DACA1-F、DAC4B(dolomite)、DAC4B-F(dolomite)、DAC4X(dolomite)、DAC4X-F(dolomite)、DAC4Z(dolomite)、DAC4Z-F(dolomite)

FFP3 NR (41 types) DTC3W、DTC3W-F、DTC3W-O、DTC3W-OF、DTC3M、DTC3M-F、DTC3M-1、DTC3M-1F、DTC3C (dolomite)、DTC3C-F(dolomite)、DTC3A、DTC3A-F、DTC3A-2F、DTCA1、DTCA1-F、DTC3R、DTC3R-F、DTC3B(dolomite)、DTC3B-F(dolomite)、DTC3XD(dolomite)、DTC3XD-F(dolomite)、DTC3Z(dolomite)、DTC3Z-F(dolomite)、DAC4、DAC4-F、DAC4M、DAC4M-F、DAC4-O、DAC4-OF、DAC4C(dolomite)、DAC4C-F(dolomite)、DAC4M-1、DAC4M-1F、DACA1、DACA1-F、DAC4B(dolomite)、DAC4B-F(dolomite)、DAC4XD(dolomite)、DAC4XD-F(dolomite)、DAC4Z(dolomite)、DAC4Z-F(dolomite)

GOGGLE (2 types) DS 8810 (Grade F)、DS 8830 (Grade B)

二、AS/NZS1716: 2003

AS/NZS 1716 LIC NO 20631

澳大利亚证书共52张(A total of 52 AS/NZS approvals)

P1 (26 types) DAC4、DAC4-F、DTC3B、DTC3B-F、DAC4B、DAC4B-F、DTC3M、DTC3M-F、DAC4M、DAC4M-F、DTC3X、DTC3X-F、DAC4X、DAC4X-F、DTCA1、DTCA1-F、DACA1、DACA1-F、DTCA1N、DTCA1N-F、DACA1N、DACA1N-F、DTC3Z、DTC3Z-F、DAC4Z、DAC4Z-F

P2 (26 types) DAC4、DAC4-F、DTC3B、DTC3B-F、DAC4B、DAC4B-F、DTC3M、DTC3M-F、DAC4M、DAC4M-F、DTC3X、DTC3X-F、DAC4X、DAC4X-F、DTCA1、DTCA1-F、DACA1、DACA1-F、DTCA1N、DTCA1N-F、DACA1N、DACA1N-F、DTC3Z、DTC3Z-F、DAC4Z、DAC4Z-F

三、NIOSH

NIOSH N95 NIOSH N99

美国N95证书共30张(A total of 30 NIOSH N95 approvals)
美国N99证书共4张（A total of 4 NIOSH N99 approvals)

N95 (30 types) DTC3W、DTC3W-F、DTC3W-O、DTC3W-OF、DTC3M-1、DTC3C-F、DTC3A、DTC3A-F、DTC3A-2F、DTCA1、DTCA1-F、DTCA1N、DTCA1N-F、DTC3B、DTC3B-F、DTC3X、DTC3X-F、DAC4、DAC4-F、DAC4C、DAC4C-F、DAC4A、DACA1、DACA1-F、DAC4X、DAC4X-F、DAC4B、DAC4B-F、DTC3Z、DTC3Z-F

N99 (4 types) DTCA1、DTCA1-F、DTCA1N、DTCA1N-F

四、FDA

FDA证书共3张(A total of 3 FDA approvals)

3-ply facemask in white/ bule/ yellow/ pink/ green，DTC3B N95, DTC3M-1 N95

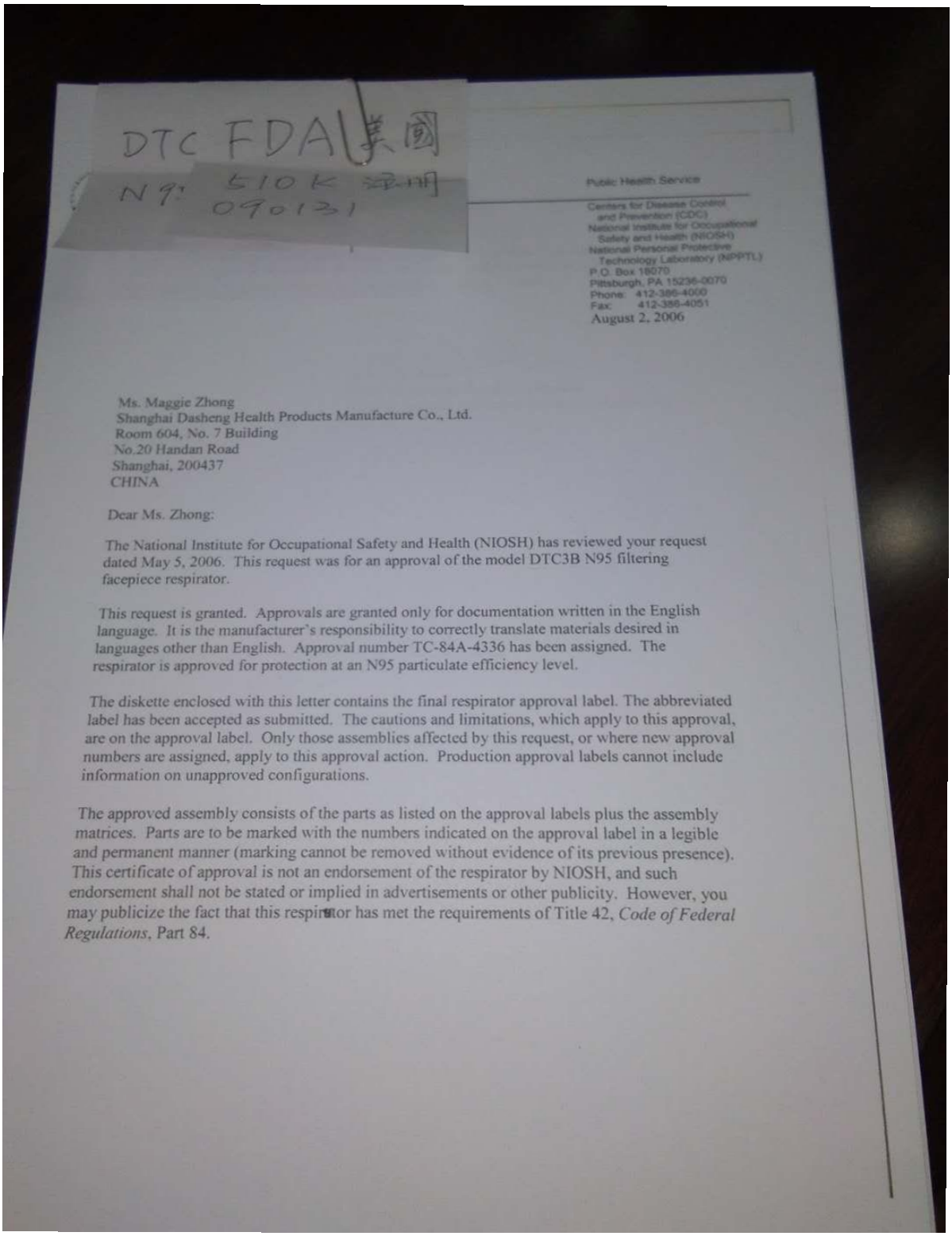
五、Japan Approved

国(平30)検第TM556号 DR捨 DS2

日本DS2证书共8张(A total of 8 DS2 approvals)

NIOSH-N95/FDA（医用 N95 口罩）DTC3B N95

NIOSH-N95 认证，FDA 注册号：510K0910131



DTC FDA 美国
N95 510K 注册
090131

Public Health Service

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

August 2, 2006

Ms. Maggie Zhong
Shanghai Dasheng Health Products Manufacture Co., Ltd.
Room 604, No. 7 Building
No.20 Handan Road
Shanghai, 200437
CHINA

Dear Ms. Zhong:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request dated May 5, 2006. This request was for an approval of the model DTC3B N95 filtering facepiece respirator.

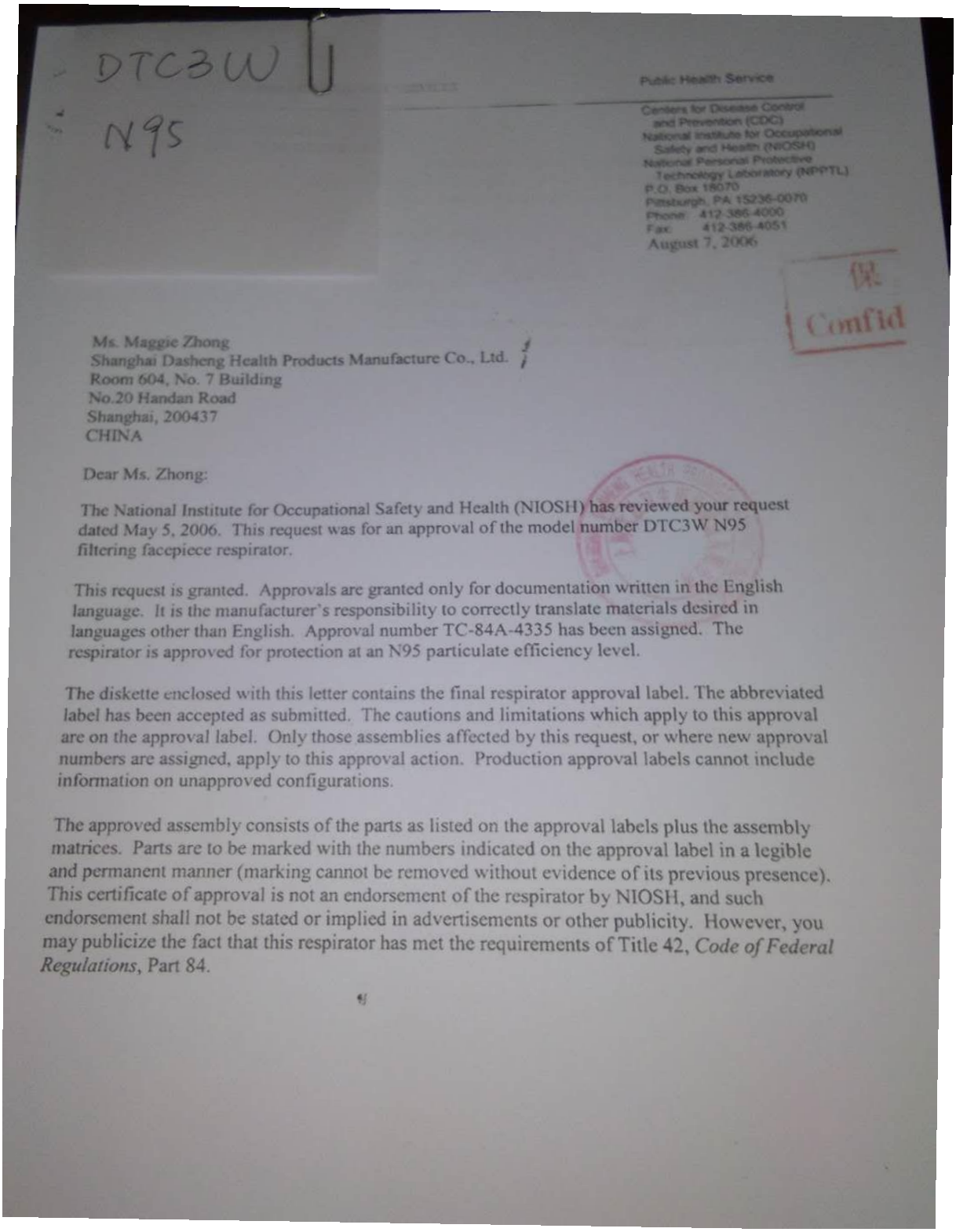
This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. Approval number TC-84A-4336 has been assigned. The respirator is approved for protection at an N95 particulate efficiency level.

The diskette enclosed with this letter contains the final respirator approval label. The abbreviated label has been accepted as submitted. The cautions and limitations, which apply to this approval, are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval labels plus the assembly matrices. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence). This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84.

NIOSH-N95（N95 口罩）DTC3W N95

NIOSH-N95 认证



DTC3W
N95

Public Health Service

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

August 7, 2006

保
Confid

Ms. Maggie Zhong
Shanghai Dasheng Health Products Manufacture Co., Ltd.
Room 604, No. 7 Building
No.20 Handan Road
Shanghai, 200437
CHINA

Dear Ms. Zhong:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request dated May 5, 2006. This request was for an approval of the model number DTC3W N95 filtering facepiece respirator.

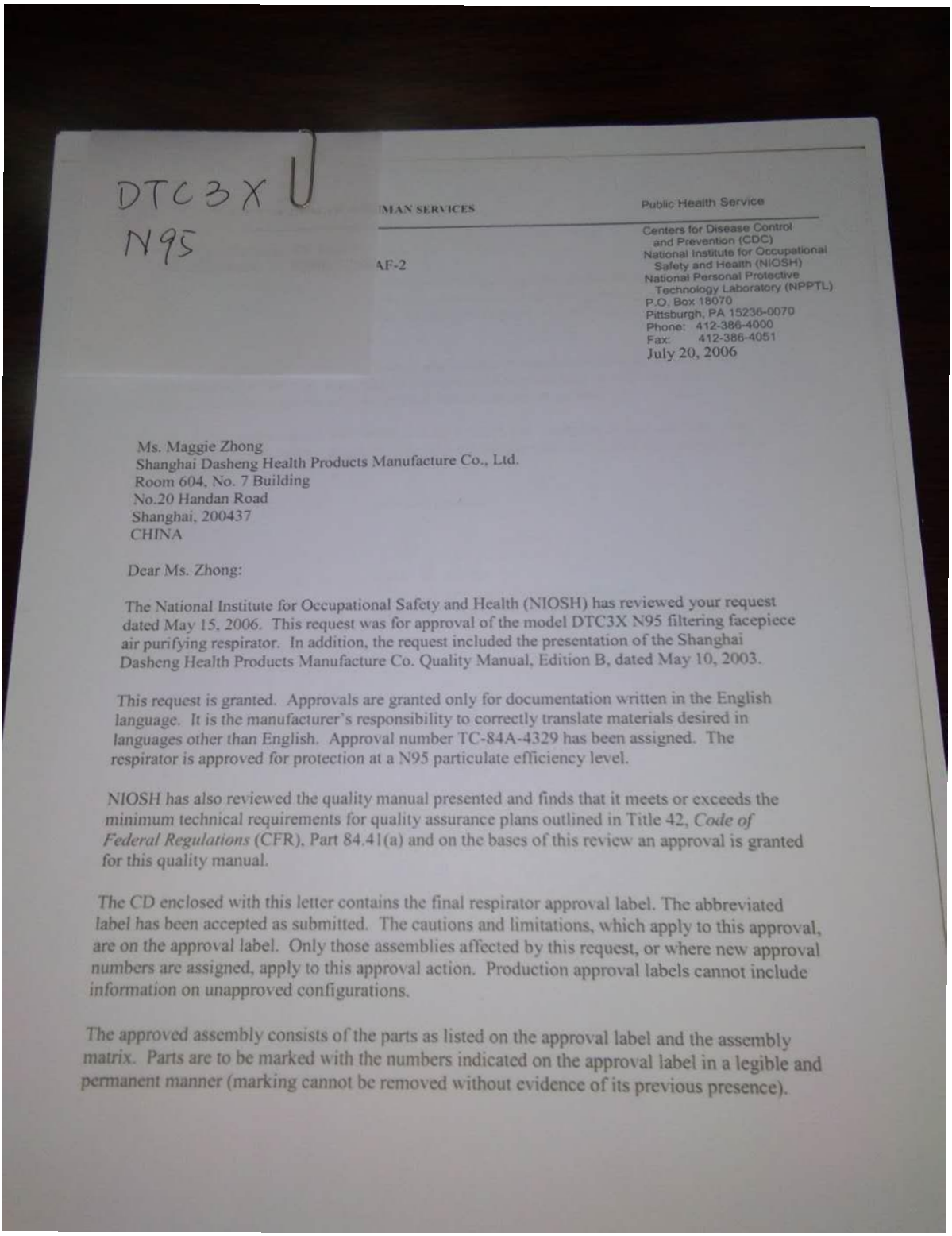
This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. Approval number TC-84A-4335 has been assigned. The respirator is approved for protection at an N95 particulate efficiency level.

The diskette enclosed with this letter contains the final respirator approval label. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval labels plus the assembly matrices. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence). This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84.

NIOSH-N95（N95 口罩）DTC3X N95

NIOSH-N95 认证



DTC3X
N95

MAN SERVICES

Public Health Service

AF-2

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

July 20, 2006

Ms. Maggie Zhong
Shanghai Dasheng Health Products Manufacture Co., Ltd.
Room 604, No. 7 Building
No.20 Handan Road
Shanghai, 200437
CHINA

Dear Ms. Zhong:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request dated May 15, 2006. This request was for approval of the model DTC3X N95 filtering facepiece air purifying respirator. In addition, the request included the presentation of the Shanghai Dasheng Health Products Manufacture Co. Quality Manual, Edition B, dated May 10, 2003.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. Approval number TC-84A-4329 has been assigned. The respirator is approved for protection at a N95 particulate efficiency level.

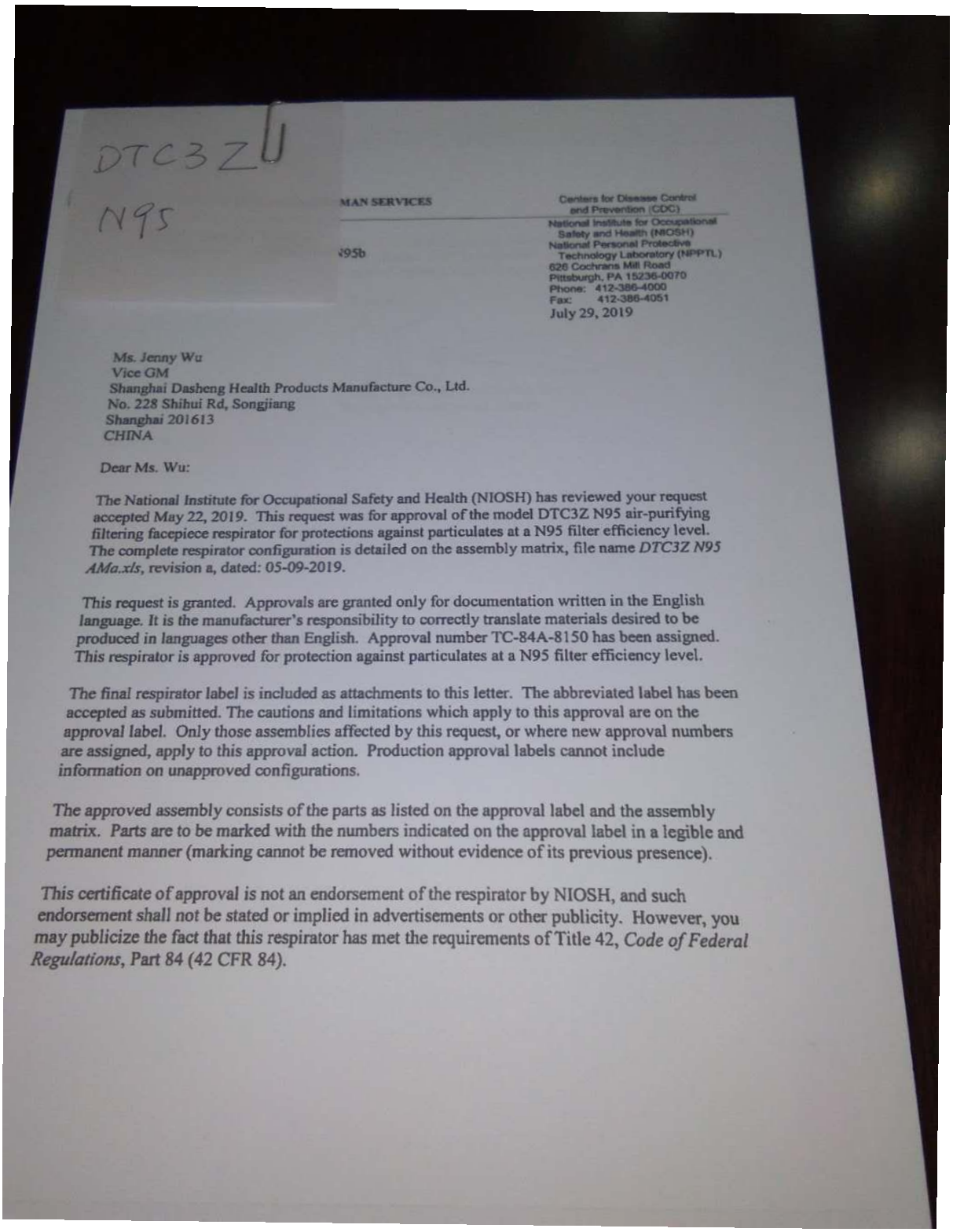
NIOSH has also reviewed the quality manual presented and finds that it meets or exceeds the minimum technical requirements for quality assurance plans outlined in Title 42, *Code of Federal Regulations* (CFR), Part 84.41(a) and on the bases of this review an approval is granted for this quality manual.

The CD enclosed with this letter contains the final respirator approval label. The abbreviated label has been accepted as submitted. The cautions and limitations, which apply to this approval, are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

NIOSH-N95（N95 口罩）DTC3Z N95

NIOSH-N95 认证



DTC3ZU
N95

MAN SERVICES

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
626 Cochrans Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

95b

July 29, 2019

Ms. Jenny Wu
Vice GM
Shanghai Dasheng Health Products Manufacture Co., Ltd.
No. 228 Shihui Rd, Songjiang
Shanghai 201613
CHINA

Dear Ms. Wu:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted May 22, 2019. This request was for approval of the model DTC3Z N95 air-purifying filtering facepiece respirator for protections against particulates at a N95 filter efficiency level. The complete respirator configuration is detailed on the assembly matrix, file name *DTC3Z N95 AMa.xls*, revision a, dated: 05-09-2019.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired to be produced in languages other than English. Approval number TC-84A-8150 has been assigned. This respirator is approved for protection against particulates at a N95 filter efficiency level.

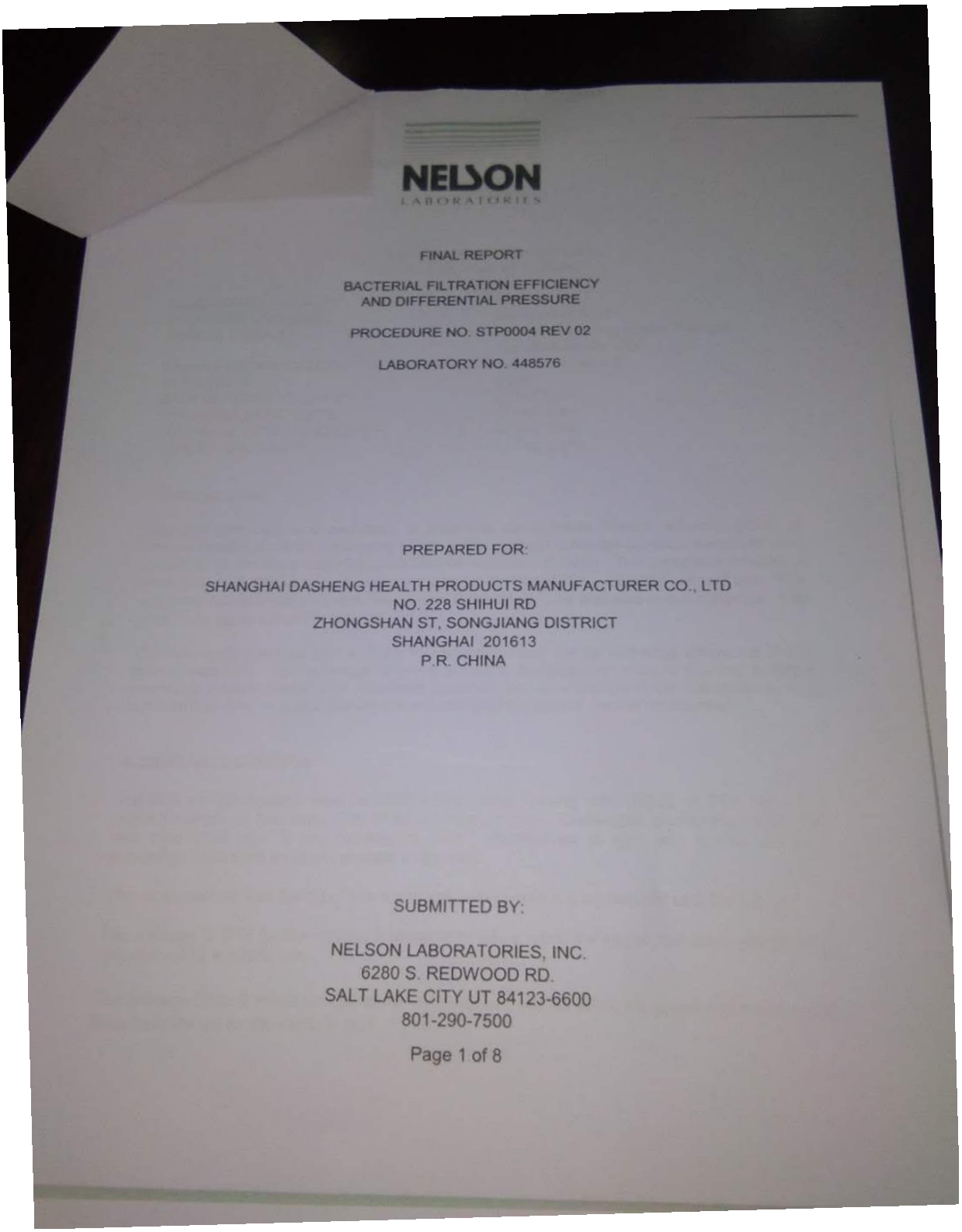
The final respirator label is included as attachments to this letter. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

NIOSH-N95（N95 口罩）带阀门

NIOSH-N95（N95 口罩）带阀门碳纤维



NELSON
LABORATORIES

FINAL REPORT

BACTERIAL FILTRATION EFFICIENCY
AND DIFFERENTIAL PRESSURE

PROCEDURE NO. STP0004 REV 02

LABORATORY NO. 448576

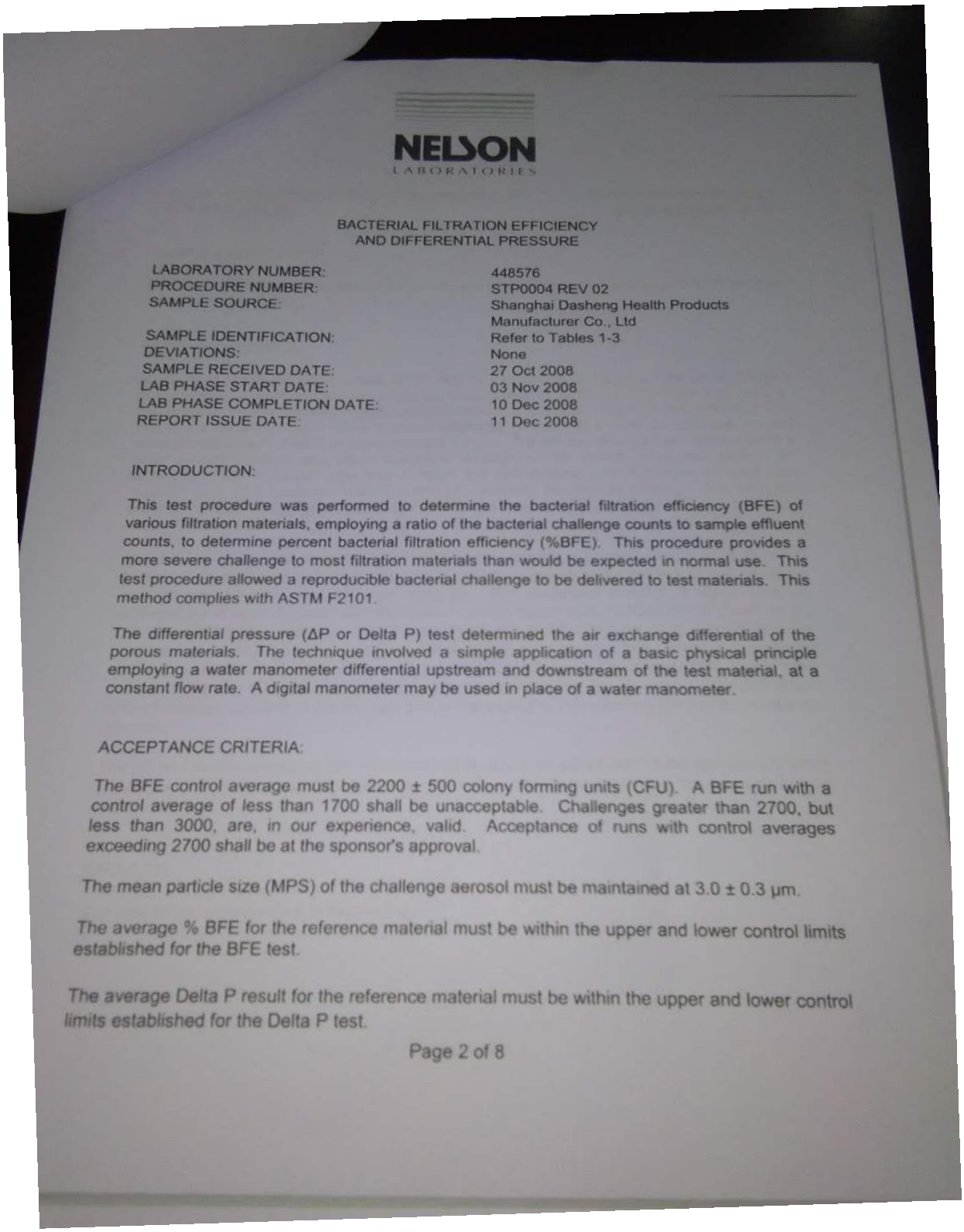
PREPARED FOR:

SHANGHAI DASHENG HEALTH PRODUCTS MANUFACTURER CO., LTD
NO. 228 SHIHUI RD
ZHONGSHAN ST, SONGJIANG DISTRICT
SHANGHAI 201613
P.R. CHINA

SUBMITTED BY:

NELSON LABORATORIES, INC.
6280 S. REDWOOD RD.
SALT LAKE CITY UT 84123-6600
801-290-7500

Page 1 of 8



NELSON LABORATORIES

BACTERIAL FILTRATION EFFICIENCY
AND DIFFERENTIAL PRESSURE

LABORATORY NUMBER:	448576
PROCEDURE NUMBER:	STP0004 REV 02
SAMPLE SOURCE:	Shanghai Dasheng Health Products Manufacturer Co., Ltd
SAMPLE IDENTIFICATION:	Refer to Tables 1-3
DEVIATIONS:	None
SAMPLE RECEIVED DATE:	27 Oct 2008
LAB PHASE START DATE:	03 Nov 2008
LAB PHASE COMPLETION DATE:	10 Dec 2008
REPORT ISSUE DATE:	11 Dec 2008

INTRODUCTION:

This test procedure was performed to determine the bacterial filtration efficiency (BFE) of various filtration materials, employing a ratio of the bacterial challenge counts to sample effluent counts, to determine percent bacterial filtration efficiency (%BFE). This procedure provides a more severe challenge to most filtration materials than would be expected in normal use. This test procedure allowed a reproducible bacterial challenge to be delivered to test materials. This method complies with ASTM F2101.

The differential pressure (ΔP or Delta P) test determined the air exchange differential of the porous materials. The technique involved a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate. A digital manometer may be used in place of a water manometer.

ACCEPTANCE CRITERIA:

The BFE control average must be 2200 ± 500 colony forming units (CFU). A BFE run with a control average of less than 1700 shall be unacceptable. Challenges greater than 2700, but less than 3000, are, in our experience, valid. Acceptance of runs with control averages exceeding 2700 shall be at the sponsor's approval.

The mean particle size (MPS) of the challenge aerosol must be maintained at 3.0 ± 0.3 µm.

The average % BFE for the reference material must be within the upper and lower control limits established for the BFE test.

The average Delta P result for the reference material must be within the upper and lower control limits established for the Delta P test.

Page 2 of 8

NELSON LABORATORIES

Shanghai Dasheng Health Products Manufacturer Co., Ltd
Lab Number 448576

Bacterial Filtration Efficiency and Differential Pressure

SAMPLE PREPARATION:

BFE test samples were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity prior to testing.

TEST PROCEDURE:

A culture of *Staphylococcus aureus*, ATCC #6538, was diluted in 1.5% peptone water (PEPW) to a precise concentration to yield challenge level counts of 2200 ± 500 CFU per test sample. The bacterial culture suspension was pumped through a 'Chicago' nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately 3.0 µm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. The collection flow rate through the test sample and Andersen sampler was maintained at 28.3 Liters per minute (Lpm) (1 cubic foot per minute (CFM)). Test samples, positive controls and reference material received a one minute challenge followed by a one minute vacuum cycle.

The delivery rate of the challenge also produced a consistent challenge level of 2200 ± 500 CFU on the test control plates. A test control (no filter medium in the airstream) and reference material are included after 5-11 test samples. The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 48 ± 4 hours and the colonies formed by each bacteria laden aerosol droplet were counted and converted to probable hit values using the hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test samples. The distribution ratio of colonies for each of the six agar plates were used to calculate the MPS of the challenge aerosol.

The ΔP test simply measured the differential air pressure on either side of the test sample using n incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 Lpm olumetric).

SULTS:

results are summarized in Tables 1-3.

NELSON
LABORATORIES

Shanghai Dasheng Health Products Manufacturer Co., Ltd
Lab Number 448576

Bacterial Filtration Efficiency
and Differential Pressure

TABLE 1. Results
Sample Identification: DS Cuped Surgical Mask

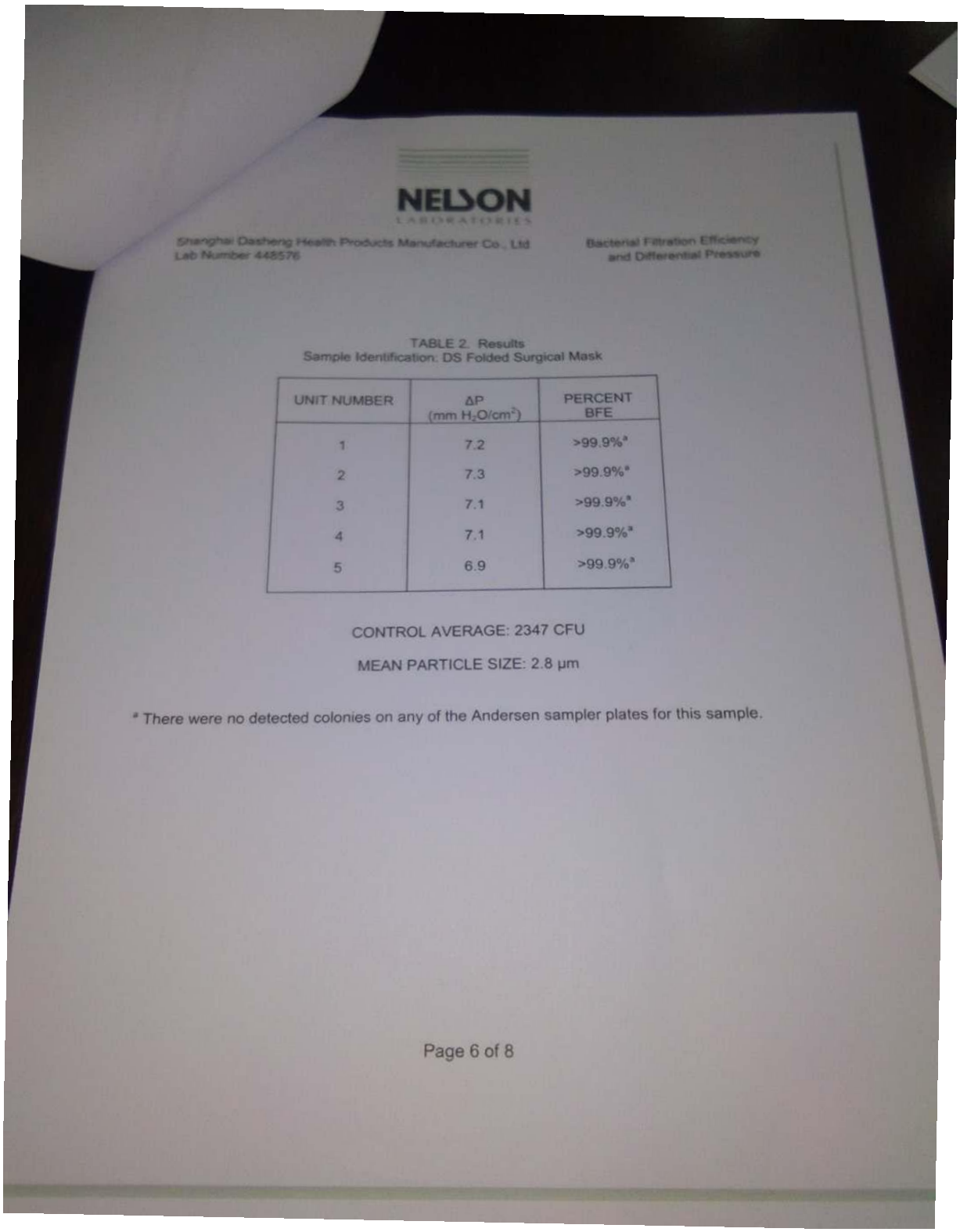
UNIT NUMBER	ΔP (mm H_2O/cm^2)	PERCENT BFE
1	7.2	>99.9%
2	6.3	>99.9%[a]
3	6.2	>99.9%[a]
4	6.8	>99.9%
5	6.2	>99.9%

CONTROL AVERAGE: 2347 CFU

MEAN PARTICLE SIZE: 2.8 µm

[a] *There were no detected colonies on any of the Andersen sampler plates for this sample.*

Page 5 of 8



NELSON
LABORATORIES

Shanghai Dasheng Health Products Manufacturer Co., Ltd
Lab Number 448576

Bacterial Filtration Efficiency
and Differential Pressure

TABLE 2. Results
Sample Identification: DS Folded Surgical Mask

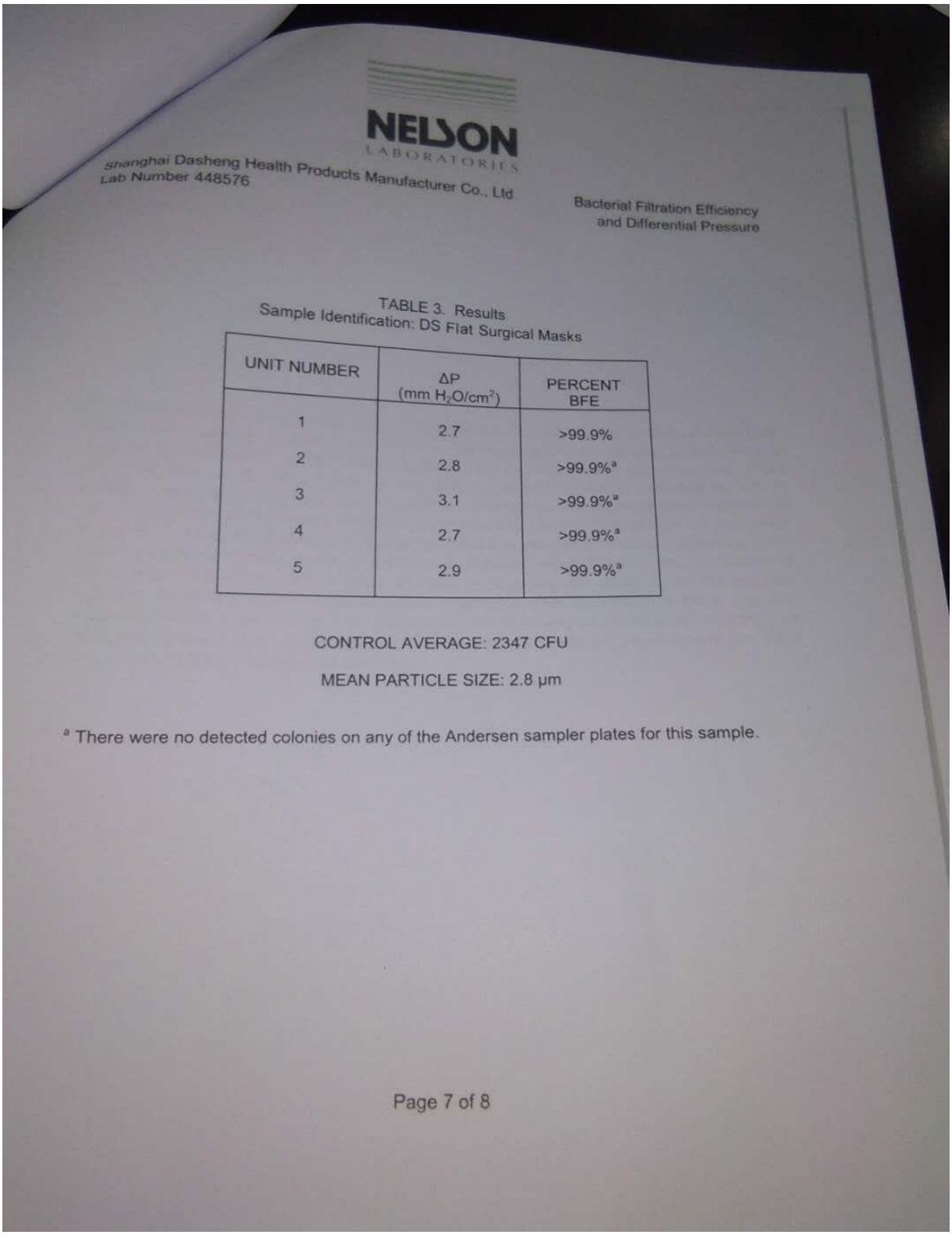
UNIT NUMBER	ΔP (mm H_2O/cm^2)	PERCENT BFE
1	7.2	>99.9%*
2	7.3	>99.9%*
3	7.1	>99.9%*
4	7.1	>99.9%*
5	6.9	>99.9%*

CONTROL AVERAGE: 2347 CFU

MEAN PARTICLE SIZE: 2.8 µm

* There were no detected colonies on any of the Andersen sampler plates for this sample.

Page 6 of 8



NELSON LABORATORIES

Shanghai Dasheng Health Products Manufacturer Co., Ltd
Lab Number 448576

Bacterial Filtration Efficiency
and Differential Pressure

TABLE 3. Results
Sample Identification: DS Flat Surgical Masks

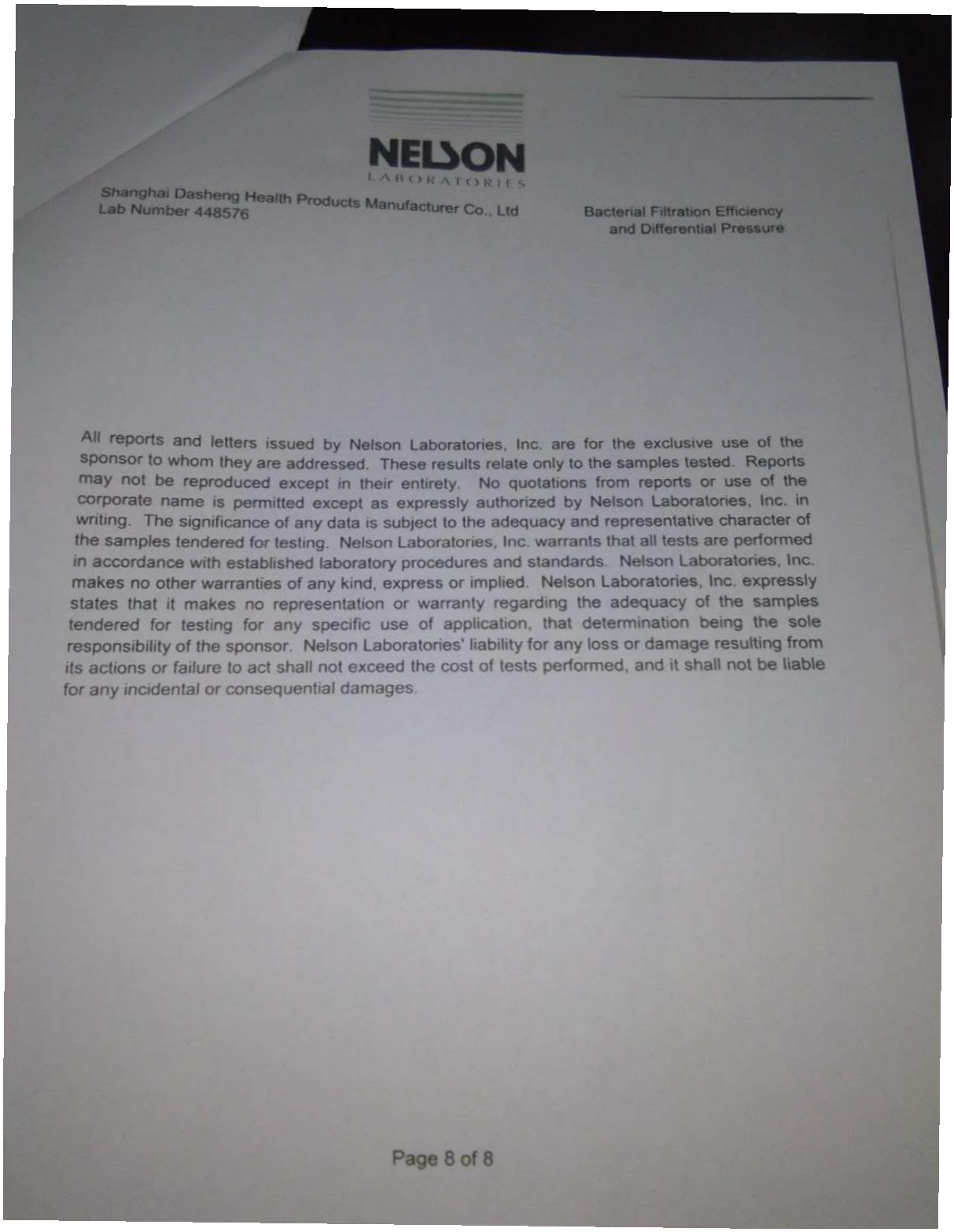
UNIT NUMBER	ΔP (mm H_2O/cm^2)	PERCENT BFE
1	2.7	>99.9%
2	2.8	>99.9%[a]
3	3.1	>99.9%[a]
4	2.7	>99.9%[a]
5	2.9	>99.9%[a]

CONTROL AVERAGE: 2347 CFU

MEAN PARTICLE SIZE: 2.8 µm

[a] There were no detected colonies on any of the Andersen sampler plates for this sample.

Page 7 of 8



NELSON
LABORATORIES

Shanghai Dasheng Health Products Manufacturer Co., Ltd
Lab Number 448576

Bacterial Filtration Efficiency
and Differential Pressure

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Page 8 of 8

Wondfo®
Leading POCT Manufacturer

COVID-19
25 tests
One Step COVID-19 Test (Immunochromatography Assay)

Contents:
1. 25 individual pouches, each containing:
   Test cassette
   Dropper
   Desiccant pouch
2. Buffer solution
3. Leaflet with instructions for use

IVD

Health

Wondfo®
One Step COVID-19 Test
(Immunochromatography Assay)
Catalog No.W105

INTENDED USE

One Step COVID-19 Test is used for detecting COVID-19 antibodies in human whole blood, serum or plasma sample, and is suitable for the preliminary screening test for the patients with suspected COVID-19 infection.

For in vitro diagnostic use only.

PRINCIPLE

One Step COVID-19 Test uses with immunochromatography assay for the detection of COVID-19 antibodies in human whole blood, serum and plasma. When the COVID-19 antibody level in the specimen is at or above the target cutoff (the detection limit of the test), the antibody bound to the antigen-dye conjugate are captured by anti-COVID-19 antibody immobilized in the Test Region (T) of the device, and this produces a colored test band that indicates a positive result. When the COVID-19 antibody level in the specimen is zero or below the target cutoff, there is

NATIVE DOCUMENT PLACEHOLDER

Please review the native document BFM000116084.mp4


20 Masks
N95 Particulate Respirator
Conforms to NIOSH N95 Standards
Provides 95% Filter efficiency
Hypoallergenic / Latex Free
High Filtration Capacity
Adjustable padded nosepiece provides comfortable fit
Disposable / Single-Use
NIOSH
MODEL NO
L-288
Harley Commodity
L-288
TC-84A-7228
NIOSH N95

- L-288 TC-84A-7228
- N95 cup type mask
- It is suitable for particle protection from buildings, mines, foundry, electronics, pharmaceuticals, physics and grinding.
- NIOSH N95 approved
  Filtration efficiency ⩾95%
- Package: 20 pcs/box, 20 boxes/carton

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

NIOSH Reference: TN-19824
Mfr. Reference: GHCL-188

December 15, 2014

Mr. Wanghua Xu
Management Representative
Guangzhou Harley Commodity Company Limited
Floor 1 to 4, #8, Team 17, Sandong Village
Xinhua Street, Huadu District
Guangzhou 510800
CHINA

Dear Mr. Xu:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted September 17, 2014. This request was for approval of the model L-188 N95 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference assembly matrix L-188 Ama.xls. In addition, the Guangzhou Harley Commodity Company QA Manual, version A1, effective date 2014-06-10, was submitted for review.

This request is granted. Approvals are granted for English language only on all documentation. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. Approval number TC-84A-6973 has been assigned. This respirator is approved for protection against particulates at a N95 filter efficiency level.

NIOSH has also reviewed the quality manual presented and finds that this manual meets or exceeds the minimum technical requirements for quality assurance plans as outlined in Title 42, *Code of Federal Regulations* (CFR), Part 84.41(a) and, on the basis of this review, this quality manual is accepted.

The CD enclosed with this letter contains the final respirator label. The abbreviated label is accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

A copy of the quality manual will be retained by NIOSH and incorporated into our files. Any future changes to this accepted quality document must be submitted to NIOSH for a modification of this accepted quality system.

Sincerely yours,

Jonathan V. Szalajda
Acting Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

NIOSH Reference: TN-19825
Mfr. Reference: GHCL-288

December 15, 2014

Mr. Wanghua Xu
Management Representative
Guangzhou Harley Commodity Company Limited
Floor 1 to 4, #8, Team 17, Sandong Village
Xinhua Street, Huadu District
Guangzhou 510800
CHINA

Dear Mr. Xu:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted September 17, 2014. This request was for approval of the model L-288 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference assembly matrix L-288 AMa.xls.

This request is granted. Approvals are granted for English language only on all documentation. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. Approval number TC-84A-7228 has been assigned. This respirator is approved for protection against particulates at a N95 filter efficiency level.

The CD enclosed with this letter contains the final respirator approval label. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely yours,

Jonathan V. Szalajda
Acting Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures


Harley Commodity
哈雷®
L-288
TC-84A-7228
NIOSH N95


KN95
N95

Shanghai Dasheng Health Products Manufacture Co.,Ltd
No.228 Shihui Road, Zhongshan Street, Songjiang District, Shanghai
Tel: 86-21-57783126 Fax: 86-57784148

510(k) Summary

APR 27 2009

This summary of 510K safety and effectiveness information is being submitted in accrodance with the requirements of 21 CFR 807.92.

The assigned 510K number is K090131

1. Submitter's Identification:

Shanghai Dasheng Health Products Manfuacture Co.,Ltd
No.228 Shihui Road, Zhongshan street, Songjiang District,
Shanghai, P.R.China

Contact:

Maggie Zhong
Tel:+86-21-33907930
Fax:+86-21-33907932
Mail:

Date of Summary: Jan 11th, 2009

2. Device Name:

DS N95 Surgical Masks and flat surgical masks

3. Classification Name: Surgical N95 Mask and flat surgical mask

4.. Device Description

The DS DTC3M-1 N95 surgical mask is constructed from a polypropylene spunbond used in the outer layer. The non-woven PP micro is the filter media and the Terylene is layered as the inner. The head strap is made of natural rubber(for double head straps) which is stapled to the mask. The inside nosepiece is a soft sponge foam.

The DS DTC3B N95 surgical mask is constructed from a polypropylene spunbond used in the outer cover, a polypropylene spunbond used in the inner cover. The non-woven PP micro fiber and polypropylene melt blown filter media is layered between the inner and out cover. The head straps are made of woven elastic strap(for single headband) which is circule to the mask. The inside nosepiece is a EVA micro-aperture foam.

The flat surgical masks (colors: blue, green, pink, white, yellow, orange) are flat pleated by 3-ply masks with outer layer and inner layers (spunbonded polypropylene) that sanwich a meltbown non-woven PP micro fibre filter material; Ear-loops are made of spandex belt for free elastic loops. The nose piece for all DS Face Masks is malleable wire. Fog free masks have an anti-fog strip. Masks with splash visors have anti-fog treated plastic shield attached to masks,All of the material used in the construction of the DS Surgical Masks are being used in currently marketed devices (see predicate information).

All items are no—sterilized and only for single use.

5. Intended Use:

DS N95 surgical masks and flat surgical mask are intended for single use by operating room personnel or general health care workers for protection against microscopic organisms, body fluids and particulates. These would include use procedure mask, isolation mask or dental face mask.

Shanghai Dasheng Health Products Manufacture Co. Ltd
No.228 Shihui Road, Zhongshan Street, Songjiang District, Shanghai
Tel: 86-21-57783126 Fax: 86-57784148

K090131

6. Comparison to Predicate Devices

DS N95 surgical masks DTC3M-1. DTC3B and flat surgical masks color pink, blue, white, green, yellow, orange are substantially equivalent is safety and effectiveness to the predicate device.

Aearo Company– K041855 Pleated plus 1050 and 1050S

Gerson Isolair Compay – K960778 APR Type N95 model 2735

Tucker & Associates company-K022256 Surgical face masks white, yellow, pink, blue and green

For reference: FXX, 878, 4040. Class II

Manufacturer	Shanghai Dasheng Health Products Manufacture Co.,Ltd	Aearo Company Predicate device-for reference
Device	DTC3B N95 Surgical Mask (New device)	Pleated plus 1050 and 1050S
510K Number	_____	K041855
Product code	MSH, 878.4040	SAME
Device Description	1. N95 Class Particuliar respirator 2. Multi-layer filteirng media (white polypropylene spundbond, Non-woven PP Micro fiber meltblown, polypropylene, polypropylene) 3. Plastic nose wire 4. White elastic headband 5. Dimension 15.5" circumference 6. Flat pleated mask 7. Single elastic head strap	1. N95 Class Particuliar respirator 2. Multi-layer filteirng media (White spundbond polypropylene, meltblown polypropylene) 3. Tie wire nose piece 4. White elastic headband 5. Dimension Small (13.5" circumference) Large(15.5" circumference) 6. Flat pleated mask 7. Dual elastic head strap
NIOSH certification#	TC-84A-4336	TC-84A-2630

Manufacturer	Shanghai Dasheng Health Products Manufacture Co.,Ltd	Gerson Isolair APR Company Predicate device-for reference
Device	DTC3M-1 N95 Surgical Mask (New device)	N95 model 2735
510K Number	_____	K960778
Product code	MSH, 878.4040	SAME
Device Description	1. N95 Class Particuliar respirator 2. Multi-layer filteirng media (white polypropylene, non-woven PP micro fiber meltblown, Terylene) 3. Plastic nose wire 4. Natural rubber, latex free 5. Dimension 15.75" circumference 6. Molded Cup 7. Dual elastic head strap	1. N95 Class Particuliar respirator 2. Multi-layer filteirng media (White nonwoven polyester meltblown polypropylene) 3. Plastic nose wire 4. Yellow elastic, latex free 5. Dimension Small (13.75" circumference) 6. Molded Cup 7. Dual elastic head strap
NIOSH certification#	TC-84A-4331	TC-84A-160

Shanghai Dasheng Health Products Manufacture Co.,Ltd K090131
No.228 Shihui Road, Zhongshan Street, Songjiang District, Shanghai
Tel: 86-21-57783126 Fax: 86-57784148

Manufacturer	Shanghai Dasheng Health Products Manufacture Co.,Ltd	Tucker & Associates company for Predicate device-for reference
Device	Flat surgical mask white, yellow, pink, blue, orange, green(New device)	Surgical Face Mask colors; white, yellow, pink, blue and green
510K Number		K022256
Product code	MSH, 878.4040	SAME
Device Description	1. Multi-layer filteirng media 2. Plastic nose wire 3. Flat pleated 4. loops or strips	1. Multi-layer filteirng media 2. Plastic nose wire 3. Flat pleated 4. loops or strip

Discussion of Non-clinical Test Performed for Determination of Substantial Equivalence are as follows:

I. NIOSH, Exhalation of Resistance Test, 84.180
II. NIOSH Inhalation of Resistance Test, 84.180
III. NIOSH Sodium Chloride (Nacl) -N95 84.181
IV. Flammibility, Complied with 16 CFR 1610 Class I,
V. Biocompatibility per ISO 10993

It is our conclusion that performance testing meet all relevant requirements of the aforementioned test standard.

Disscussion of Clinical Tests Performed.

Not Applicable

7. Conclusions

DS N95 Surgical Masks, DTC3M-1, DTC3B and flat surgical masks have the same intended use and technology characterisitics as the predicate devices (K041855, K960778, K022256). Moreover, the bench testing contained in this submission supplied domonstrate that the technological characterisistics do not raise any new question of safety or effectiveness.

DS N95 Surgical Masks, DTC3M-1, DTC3B and flat surgical masks are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2009

Ms. Maggie Zhong
Shanghai Dasheng Health Products
Number 228 Shihui Road Zhongshan Street
Songjiang District
Shanghai, CHINA

Re: K090131
Trade/Device Name: DS N95 Surgical Masks and Flat Surgical Masks for Single Use
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH, FXX
Dated: April 8, 2009
Received: April 13, 2009

Dear Ms. Zhong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

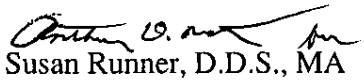
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment A

INDICATIONS FOR USE

510(k) NUMBER (IF KNOWN): K090131

APPLICANT: **Shanghai Dasheng Health Products Manufacture Co.,Ltd**

DEVICE NAME:

DS N95 Surgical Masks and Flat Surgical Masks for single use

DTC3M-1, DTC3B Surgical N95 Respirator

DS Surgical Ear- Loop Masks – Blue(FE3B), Pink(FE3P), Green(FE3G), Yellow(FE3Y), White(FE3W), Orange(FE3O)

DS Surgical Fog Free Ear-Loop Masks- Blue(FE3B-O), Pink(FE3P-O), Green(FE3G-O), White(FE3W-O), Orange(FE3O-O), Yellow(FE3Y-O),

DS Surgical Ear-Loop Masks with splash visor – Blue(FE3B-A), Pink(FE3P-A), Orange(FE3O-A), white(FE3W-A), Yellow(FE3Y-A), Green(FE3G-A)

DS Surgical Tie-On Masks – Blue(FT3B), Pink(FT3P), Green(FT3G), Yellow(FT3Y), White(FT3W), orange(FT3O)

DS Surgical Fog Free Tie-On Masks - Blue(FT3P-O), Pink(FT3P-O), Green(FT3G-O), Yellow(FT3Y-O), White(FT3W-O), Orange(FT3O-O)

DS Surgical Tie-On Masks with splash visor - Blue(FT3B-A), White(FT3W-A), Orange(FT3O-A), Yellow(FT3Y-A), Pink(FT3P-A), Green(FT3G-A)

INDICATION FOR USE:

The DS N95 Surgical Masks DTC3M-1/DTC3B, and flat surgical masks are intended for single use by operating room personnel and other health care workers to protect both the patients and the health care workers from transfer of microorganisms, blood and body fluids, and airborne particulate materials.

Prescription Use _____ AND/OR Over-The-Counter Use X

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090131

People's Republic of China Medical Device Registration Certificate

(In Vitro Diagnosis Test)

Registration No.: GuoXieZhuZhun 20203400176

Registrant Company	Guangzhou Wondfo Biotech Co., Ltd.
Registrant Address	No. 8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China
Manufacturing Address	No. 8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China
Agent	None
Agent Address	None
Product Name	SARS-CoV-2 Antibody Test (Lateral flow method)
Package Specification	Cassette: 1 test/pouch, 1 test/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 40 tests/kit, 50 tests/kit.
Main Content	Test cassette, sample diluent (dropping bottle) and sample dropper. (See the instructions for details).
Intended Use	This product is an immunochromatographic assay for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgG/IgM antibody in human whole blood, serum or plasma sample. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2. The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision.
Appendix	Product Specifications, Instructions
Storage and Shelf Life	Store the cartridges and buffer at 2-30℃, the shelf life is tentatively determined to be 6 months.
Other content	None
Remark	Registrant are required to finish the following tasks after product launch: 1. This product is only a supplementary diagnosis and emergency reserve for pneumonia infected by COVID-19. The registration certificate is valid for 1 year. 2. When renewing registration, a summary report of clinical application data should be submitted in accordance with the

	following requirements: continuous clinical application data of the product should be collected at 3 or more clinical medical institutions (including centers for disease control and prevention at all levels). The clinical application data should be completed, the sample size should meet the statistical requirements, and the signature and seal should meet the requirements. 3. The enterprise shall finish all registration application materials in accordance with *In Vitro Diagnostic Reagent Registration Management Method* when renewing registration.

Approved by: National Medical Products Administration

Approval Date: 22nd February 2020

Valid Until: 21st February 2021