NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Shandong Sino Medical Equipment Co., Ltd.
Model Tested: D918
Date Tested: May 13, 2020

These findings pertain to the Shandong Sino Medical Equipment Co., Ltd., model D918. The packaging for these respirators indicate they meet GB19083-2010 (the Chinese standard for Technical Requirements for Protective Face Mask for Medical Use).

Ten respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. This modified assessment plan can be found here.

No certificate of approval was provided with the samples received; therefore, the authenticity of the claims cannot be validated.

The maximum and minimum filter efficiency was 98.35% and 97.15%, respectively. All ten respirators measured more than 95%.

While the above-listed product classification has similar performance requirements to NIOSH-approved devices, NIOSH does not have knowledge about the sustained manufacturer quality system and product quality control for these products. NIOSH also does not have knowledge about the product's handling and exposures after leaving its manufacturer's control.

In addition, this product is an ear loop design. Currently, there are no NIOSH-approved products with ear loops; NIOSH-approved N95s have head bands. Furthermore, limited assessment of ear loop designs, indicate difficulty achieving a proper fit. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved.

This assessment is not a part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process. This assessment was developed as an assessment of the filter efficiency for those respirator's represented as certified by an international certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers due to the respirator shortage associated with COVID-19. Only particulate filter efficiency was assessed.

The results provided in this letter are specific to the subset of samples that were provided to NPPTL for evaluation.

These results will be used to update the CDC guidance for Crisis Capacity Strategies (during known shortages).

Evaluation of International Respirators

NPPTL
National Personal Protective Technology Laboratory

Test: Modified TEB-APR-STP-0059

Date Tested: May 13, 2020

Report Prepared: May 13, 2020

Manufacturer: Shandong Sino Medical Equipment Co., Ltd.

Item Tested: D918

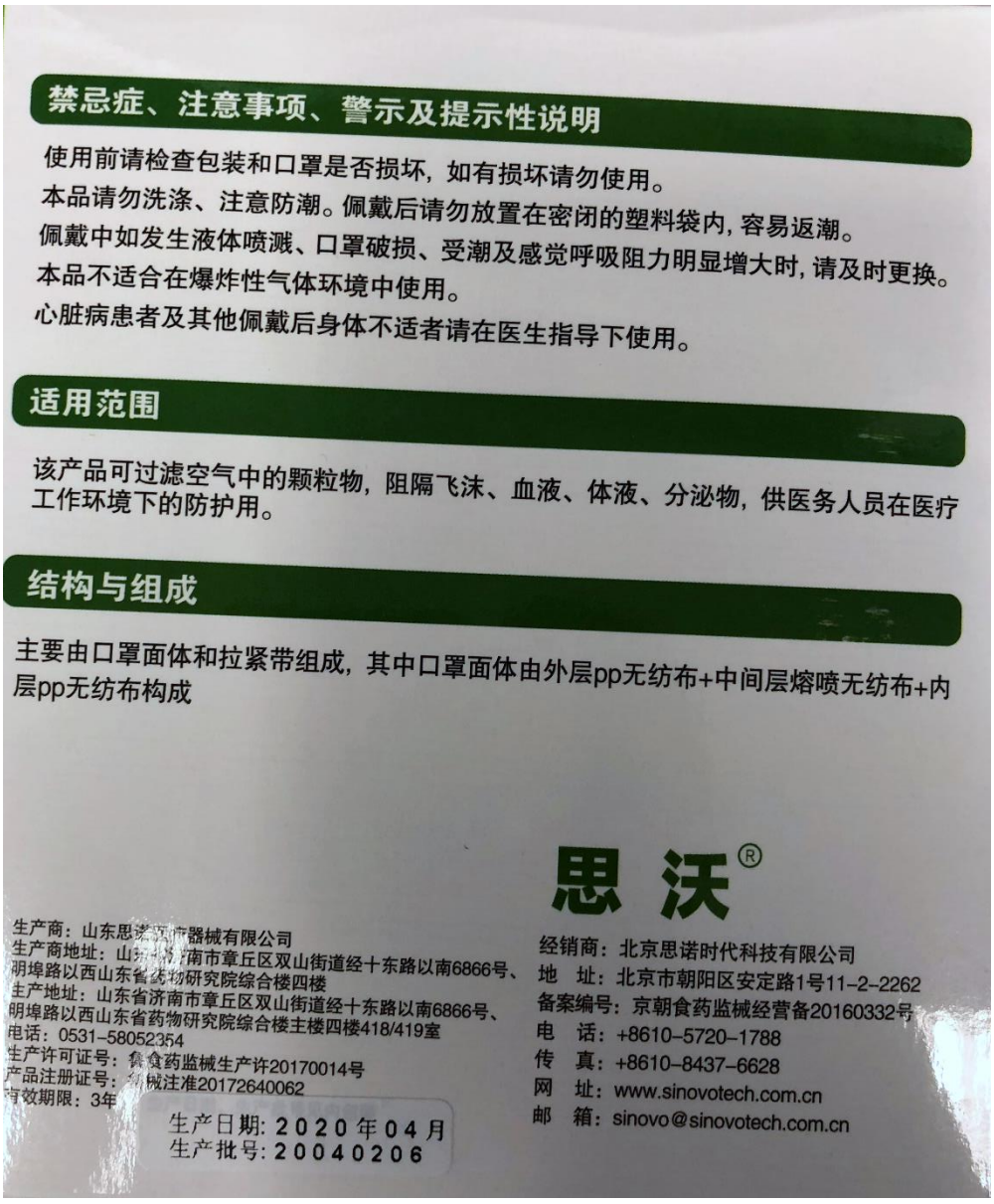
Country of Certification: China (GB19083-2010)

Pictures have been added to the end of this report.

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	7.3	2.43	2.43	97.57
2	85	7.1	1.59	1.65	98.35
3	85	8.9	1.75	1.77	98.23
4	85	8.2	1.87	1.94	98.06
5	85	8.7	2.02	2.02	97.98
6	85	9.0	1.99	1.99	98.01
7	85	7.3	2.26	2.34	97.66
8	85	7.4	2.03	2.06	97.94
9	85	8.3	2.81	2.85	97.15
10	85	8.6	2.24	2.24	97.76
Minimum Filter Efficiency: 97.15			**Maximum Filter Efficiency: 98.35**		

- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- Respirators tested may not be representative of all respirators with the same certification mark. NIOSH has no control over suppliers and distributors of respirators certified by other national or international parties.
- This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
- This assessment was not a part of the NIOSH approval program. These results do not imply nor preclude a future approval through the NIOSH respirator approval program.


MTT-2020-134
思沃®
医用防护口罩
Medical Protective Respirator
采用N95等级滤料
D918
高密闭 高防护
防PM0.3
对0.3um 颗粒物的防护效率高达95%
其他大小颗粒防护效率更高
执行最新国家标准GB19083-2010
20只装



禁忌症、注意事项、警示及提示性说明

使用前请检查包装和口罩是否损坏，如有损坏请勿使用。
本品请勿洗涤、注意防潮。佩戴后请勿放置在密闭的塑料袋内，容易返潮。
佩戴中如发生液体喷溅、口罩破损、受潮及感觉呼吸阻力明显增大时，请及时更换。
本品不适合在爆炸性气体环境中使用。
心脏病患者及其他佩戴后身体不适者请在医生指导下使用。

适用范围

该产品可过滤空气中的颗粒物，阻隔飞沫、血液、体液、分泌物，供医务人员在医疗工作环境下的防护用。

结构与组成

主要由口罩面体和拉紧带组成，其中口罩面体由外层pp无纺布+中间层熔喷无纺布+内层pp无纺布构成

思沃®

生产商：山东思诺[illegible]器械有限公司
生产商地址：山[illegible]南市章丘区双山街道经十东路以南6866号、明埠路以西山东省药物研究院综合楼四楼
生产地址：山东省济南市章丘区双山街道经十东路以南6866号、明埠路以西山东省药物研究院综合楼主楼四楼418/419室
电话：0531-58052354
生产许可证号：鲁食药监械生产许20170014号
产品注册证号：[illegible]械注准20172640062
有效期限：3年

生产日期：2020年04月
生产批号：20040206

经销商：北京思诺时代科技有限公司
地　址：北京市朝阳区安定路1号11-2-2262
备案编号：京朝食药监械经营备20160332号
电　话：+8610-5720-1788
传　真：+8610-8437-6628
网　址：www.sinovotech.com.cn
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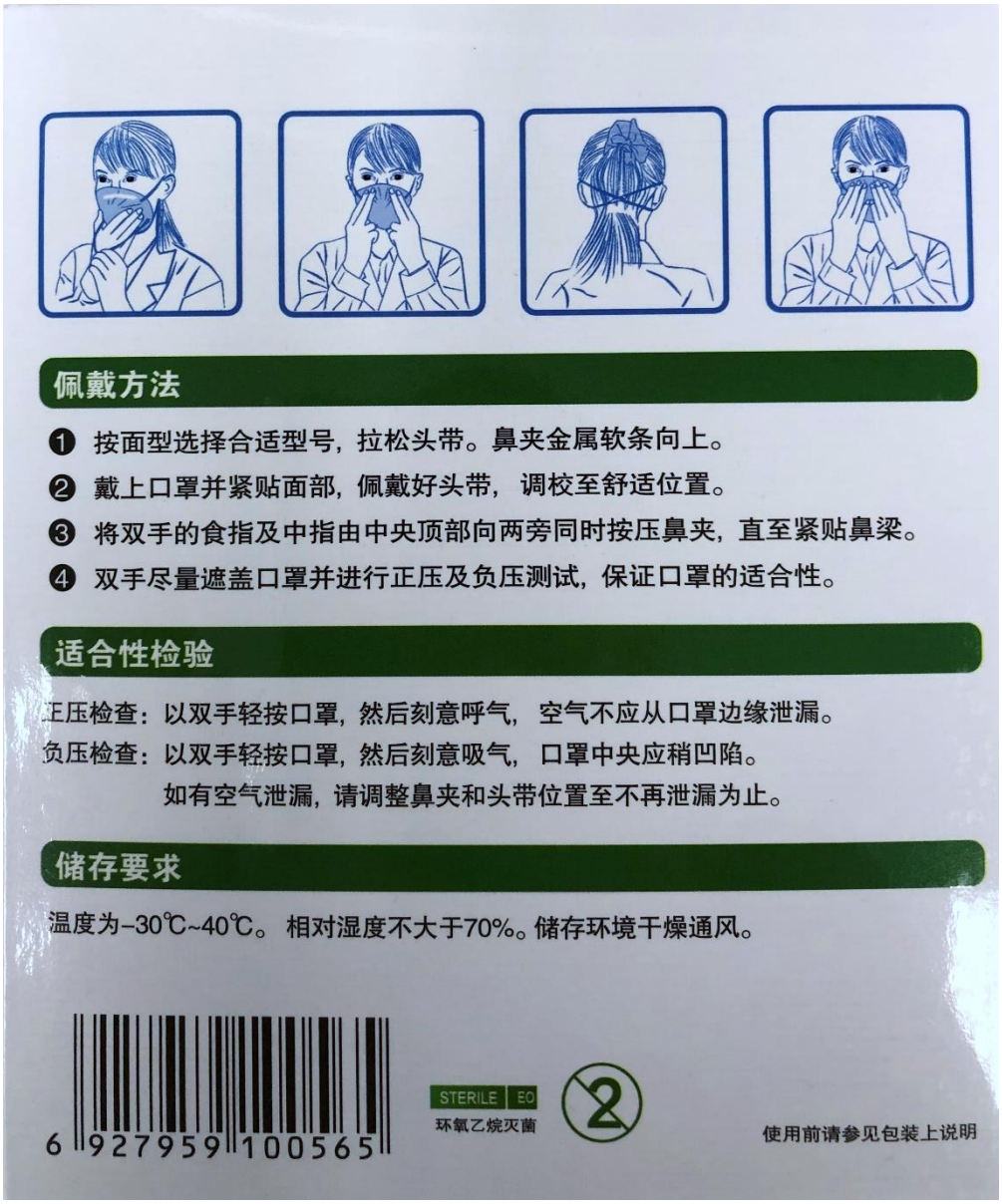

佩戴方法

❶ 按面型选择合适型号，拉松头带。鼻夹金属软条向上。
❷ 戴上口罩并紧贴面部，佩戴好头带，调校至舒适位置。
❸ 将双手的食指及中指由中央顶部向两旁同时按压鼻夹，直至紧贴鼻梁。
❹ 双手尽量遮盖口罩并进行正压及负压测试，保证口罩的适合性。

适合性检验

正压检查：以双手轻按口罩，然后刻意呼气，空气不应从口罩边缘泄漏。
负压检查：以双手轻按口罩，然后刻意吸气，口罩中央应稍凹陷。
如有空气泄漏，请调整鼻夹和头带位置至不再泄漏为止。

储存要求

温度为-30℃~40℃。相对湿度不大于70%。储存环境干燥通风。

6 927959 100565

STERILE EO
环氧乙烷灭菌

使用前请参见包装上说明


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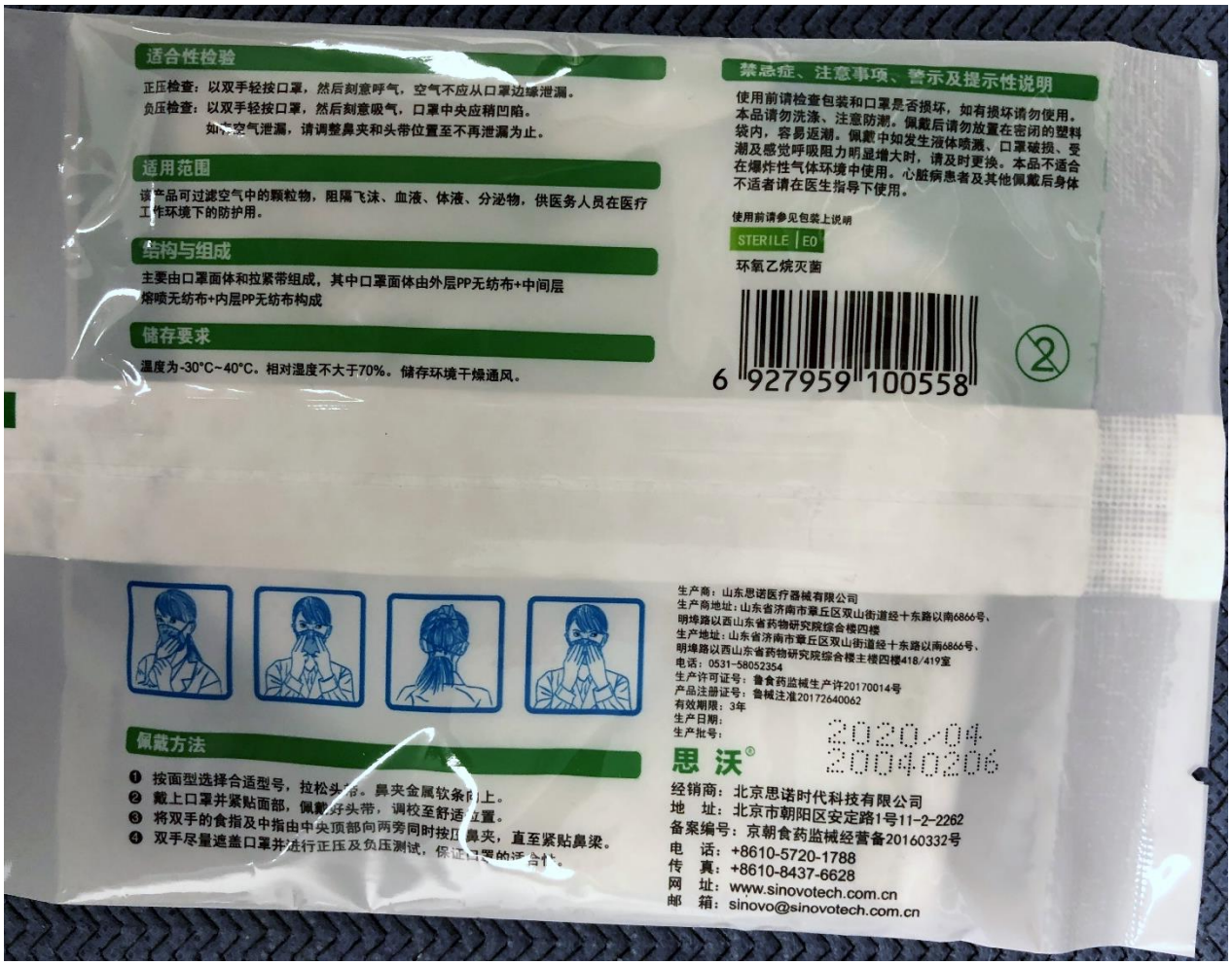
思沃®
医用防护口罩
Medical Protective Respirator
采用N95等级滤料
D918
高密闭 高防护
防PM0.3
对0.3um颗粒物的防护效率高达95%
其他大小颗粒防护效率更高
1只装
高危环境累计使用40小时
执行标准GB19083-2010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如有空气泄漏，请调整鼻夹和头带位置至不再泄漏为止。
适用范围
该产品可过滤空气中的颗粒物，阻隔飞沫、血液、体液、分泌物，供医务人员在医疗工作环境下的防护用。
结构与组成
主要由口罩面体和拉紧带组成，其中口罩面体由外层PP无纺布+中间层熔喷无纺布+内层PP无纺布构成
储存要求
温度为-30°C~40°C。相对湿度不大于70%。储存环境干燥通风。
禁忌症、注意事项、警示及提示性说明
使用前请检查包装和口罩是否损坏，如有损坏请勿使用，本品请勿洗涤、注意防潮。佩戴后请勿放置在密闭的塑料袋内，容易返潮。佩戴中如发生液体喷溅、口罩破损、受潮及感觉呼吸阻力明显增大时，请及时更换。本品不适合在爆炸性气体环境中使用。心脏病患者及其他佩戴后身体不适者请在医生指导下使用。
使用前请参见包装上说明
STERILE EO
环氧乙烷灭菌
6 927959 100558
佩戴方法
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❸ 将双手的食指及中指由中央顶部向两旁同时按压鼻夹，直至紧贴鼻梁。
❹ 双手尽量遮盖口罩并进行正压及负压测试，保证口罩的适合性。
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电话：0531-58052354
生产许可证号：鲁食药监械生产许20170014号
产品注册证号：鲁械注准20172640062
有效期限：3年
生产日期：2020-04-20
生产批号：20040206
思沃®
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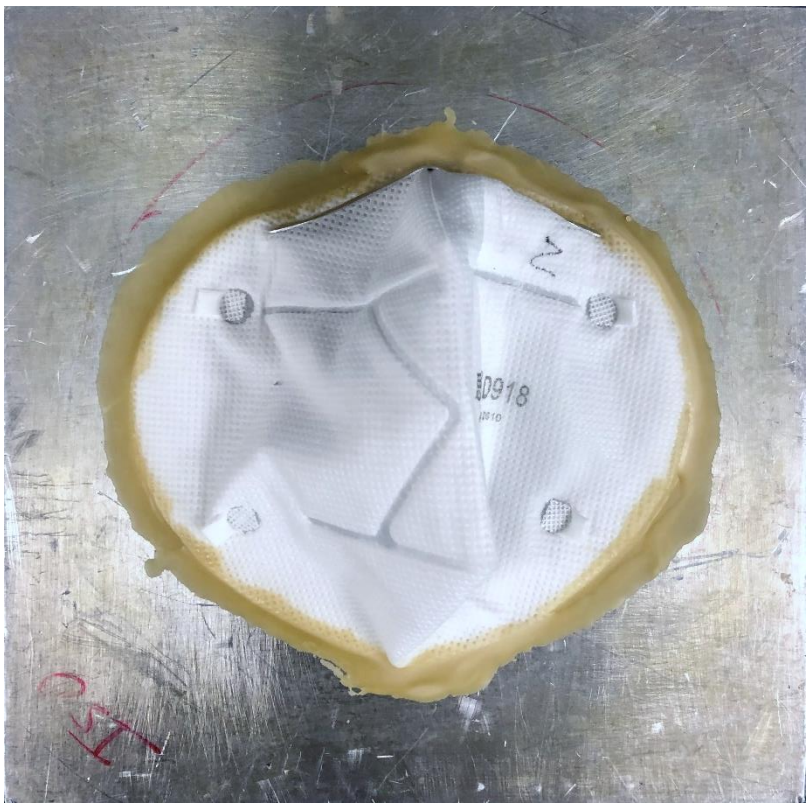
思沃® D918
GB19083-2010


思沃® D918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