RYZUR

10 May 2020

Declaration Letter

Regarding CDC and Its Subdivisions' Assessment and Conclusion Regarding Suspected Counterfeit RYZUR Medical Respirator Product

Dear consumers, distributors and business partners:

Recently, we have learned that a suspected counterfeit RYZUR medical respirator product was assessed as unqualified by a subdivision of the Centers for Disease Control and Prevention ("**CDC**"), and been actively taking measures to deal with this issue. To clarify relevant facts and to protect RYZUR's reputation as well as interests of our consumers, distributors and partners, we hereby issue this declaration letter for your information.

1. Relevant Facts

On 4 May 2020, CDC issued an article titled "NPPTL Respirator Assessments to Support the COVID-19 Response"[1] on the website of National Personal Protective Technology Laboratory ("**NPPTL**") which belongs to a CDC subdivision, the National Institute for Occupational Safety and Health ("**NOISH**"). This article provides the assessment results (not NOISH-approved) for some international brands' products collected by them, which states that a respirator manufactured by Anhui RYZUR Medical Equipment Manufacturing Co., Ltd. ("**Anhui RYZUR**") was tested and deemed unqualified due to low filter efficiency. Anhui RYZUR is wholly owned by Beijing RYZUR Medical Investment Co., Ltd ("**RYZUR Medical**"). Anhui RYZUR and Beijing Ruishan Bozhong Medical Equipment Co., Ltd. are both wholly-owned subsidiaries of RYZUR Medical, and both produce personal protective products.

After discovering the foregoing, RYZUR Medical prioritized a response to it, and

[1] https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html

promptly organized relevant personnel from production, quality and sales departments to discuss and review the test result and assessment report published by CDC/NOISH/NPPTL. We found that the product in question is a suspected counterfeit respirator labelled "RYZUR Medical". At first glance, the package of this product is similar to that of Anhui RYZUR's product sold in China. However, the appearance and package of the product is different from and inferior to that of Anhui RYZUR's bona fide product. Moreover, Anhui RYZUR never officially sold this type of product in the U.S. market.

With a cautious and responsible attitude, RYZUR Medical promptly took responsive actions, and communicated directly with CDC/NIOSH/NPPTL by phone and emails between 5 and 7 May 2020. Through those communications, RYZUR Medical learned, among other things, that:

First, CDC/NIOSH/NPPTL replied that they had been informed that many manufacturers in China have been counterfeited.

Second, CDC/NIOSH/NPPTL confirmed that the tested samples of so-called Anhui RYZUR's product were provided by a worker in the United States without any specific accompanying information. CDC/NIOSH/NPPTL did not have information regarding the source, importer, supplier or distributor of the samples. In other words, the source of tested samples is unknown.

RYZUR has been operating in Chinese medial industry for nearly 15 years, and has more than five self-operated and cooperative hospitals with over 2,000 beds in China, as well as two medical device production facilities in Hefei, Anhui Province and Beijing. The employees of RYZUR's hospitals and companies exceed 2,000 persons, not including its employees in its personal protective equipment department. In the battle against COVID-19 in China, RYZUR's doctors and staff always stand on the front line and contribute positively to the efforts to control and prevent further spread of the disease. RYZUR's newly established personal protective equipment department (respirator production) and cooperating manufacturers currently have more than 1,000 employees. We always implement strict quality control standard and procedures

throughout our respirator production facilities. In the context of the global outbreak of COVID-19, RYZUR deeply understands that the quality of our product impacts not only the health, but also the lives of users.

Moreover, Anhui RYZUR has strict regulations on raw material inspection, supplier examination, inspection of semi-finished products and inspection of finished products. Before a respirator product is sent out of YZUR's factory, strict product inspections must be conducted and completed. Any unqualified product would never be approved for sale. In order to further assess the product, RYZUR tested the retained samples of relevant products, samples of raw materials and record of test files of the batch. The retained samples of related products, test files and production records show that RYZUR's products have never been tested to have 30% NACL particulates under 85L flow rate. In the wake of the CDC statements, RYZUR Medical conducted another sample test on retained product samples, and according to those test results, no sample had a filtration efficiency at or around 30%.

In order to further carry out a product test, Anhui RYZUR entrusted the subsidiary of RYZUR Medical, Beijing Ruishan Bozhong Medical Equipment Co., Ltd., to conduct another method adjustment test on 8 May 2020 Beijing time. The test was conducted **with all raw material unchanged, and without the filter layer (melt-blown layer or nanomaterial layer) which would normally be filled into the KN95 masks manufactured by RYZUR Medical**. The test result shows that the filtration efficiency was still about 68%. To further test the quality of our product, we filled **a normal napkin** into a KN95 mask with its filter layer (meltblown layer or nanomaterial layer) completely removed, and the result showed that the filtration efficiency was approximatly74%.

Therefore, it can be concluded that the product tested by NPPTL is an extremely low-quality counterfeit of RYZUR's products.

Furthermore, during the epidemic period, RYZUR Medical applied to DKERA Testing and Certification GmbH, an authoritative test agency in Germany, to conduct an urgent European coronavirus PPE (personal protective equipment) test on RYZUR's respirator

products. Those test results showed that Anhui RYZUR's respirator products fully comply with the qualifying standard and with a filtration efficiency exceeding 98%.

2. Clarification and Declaration on Relevant Matters

RYZUR Medical believes that the above practice of CDC/NIOSH/NPPTL is not rigorous or reasonable. These institutions state on their website that they "**make no representation as to the authenticity of the samples received and assessed**". But if the test samples are not traceable, the tests conducted does not comply with the general standards and practice of a product test. These institutions conducted so-called "assessments" without any knowledge of the source and authenticity of their samples, but published test results of those samples identifying them as originating with the manufactures of the authentic products. Those actions have caused and continue to cause serious damage to the reputation of RYZUR and products manufactured in China, have misled the market, and resulted in other severe impacts to RYZUR.

RYZUR Medical is fully confident in the quality of its products. In light of the above circumstances, RYZUR Medical has engaged lawyers practicing in the United States and China to represent it with respect to the CDC/NIOSH/NPPTL issue and to take all necessary and available legal measures on its behalf. RYZUR will endeavor to defend its reputation and legitimate interest, and to safeguard the interests of its consumers, distributors and partners.

Yours faithfully,

Beijing RYZUR Medical Investment Co., Ltd.

Anhui RYZUR Medical Equipment Manufacturing Co., Ltd.