



TNI medical cleared to enter the US market

Wuerzburg, November 21, 2018 - TNI medical AG, based in Wuerzburg, Germany, has received official clearance to sell its *TNI softFlow 50* high-flow ventilator in the USA. The U.S. Food and Drug Administration (FDA) has granted the company clearance for the use of *TNI softFlow 50* to treat all adult patients who would benefit from receiving high flow warmed and humidified respiratory gases. The clearance covers use of the devices during inpatient treatment. The devices can be put into operation in US hospitals effective immediately.

Ewald Anger, CEO of TNI medical, says: "In the USA about 12 million people are treated with high flow warmed and humidified respiratory gases each year. With the clearance of the *TNI softFlow 50*, we can help alleviate their breathing difficulties with our innovative high-flow respirators. So, the successful completion of the FDA clearance process is a major and important milestone in our growth strategy. Owing to its low noise level, autonomous supply of water and air, high efficiency and low weight, the *TNI softFlow* device is ideal for treating suitable patients inside or outside the intensive care unit. We therefore expect this to further accelerate our internationalization process. We also expect the *TNI softFlow* to be approved in other markets in the near future, specifically in the large Chinese market."

In many respiratory illnesses, the functioning of the lungs is considerably compromised and can no longer adequately provide for the exchange of oxygen and carbon dioxide. According to current figures from the World Health Organization (WHO), respiratory illnesses afflict hundreds of millions of people around the world and are among the commonest causes of death worldwide. Experts predict that the number of patients with respiratory diseases will continue to rise globally. The need for effective and, above all, more comfortable treatment options is therefore continuously increasing. Patients are generally averse to today's standard treatment methods, which consist of closed nose or face masks.

The ventilators in the *TNI softFlow* family provide respiratory patients a warm, moist air flow directly into the nose through a thin, heated and noise-optimized nasal cannula without condensation. The air flow rate and humidity can be precisely adjusted and, if necessary, oxygen can be added. This results in effective patient treatment. The products are also simple to use, as the nasal cannula is easy to put on and take off. Patients have complained of the limited comfort afforded by many conventional ventilators with closed nose and face masks. During treatment with TNI ventilators, patients can continue to perform everyday tasks such as eating, drinking, speaking or taking medication. TNI medical's novel treatment method not only achieves very good clinical results, but also provides better tolerability for patients compared to traditional mask therapy.



About TNI medical AG

TNI medical AG develops, produces and sells respiratory therapy devices for patients with respiratory illnesses such as chronic obstructive pulmonary disease (COPD). For over ten years now, the Wuerzburg-based company has focused on a single goal: the consistent further development of nasal high-flow treatment to offer respiratory support with maximum efficiency and comfort to patients with respiratory insufficiency. Based on intensive research and realized through precise development work in treatment with nasal insufflation (TNI), the TNI softFlow system generation offers the highest treatment quality, both at the hospital and at home.