**TÜV Rheinland certifies according to EU Medical Devices Regulation**

TÜV Rheinland can issue MDR certification to importer of respirators, resuscitators and neonatal ventilation equipment / [www.tuv.com/mdr](http://www.tuv.com/mdr)

**Cologne, 30 August 2023.** TÜV Rheinland, one of the world’s leading providers of testing and certification services, has granted Taiwanese medical device manufacturer GaleMed certification in accordance with the new EU Medical Devices Regulation (MDR). GaleMed produces respiratory care interface technology such as neonatal and prenatal ventilation. With the current certification, GaleMed and TÜV Rheinland are making an important contribution to the operational implementation of the MDR.

As part of EU reforms in recent years, the Medical Device Directive (MDD) has been upgraded to the Medical Device Regulation (MDR), which significantly increases the requirements for safety, performance, clinical evaluation and life cycle of medical devices. As a result, manufacturers and distributors must comply with stricter requirements in terms of standards, quality and market surveillance.

Recently, manufacturers and importers, as well as physicians, have increasingly pointed out the difficulties in implementing the new requirements and warned of possible shortages of medical devices, especially in the field of paediatrics. Earlier this year, the European Commission held out the prospect of extending the transition periods.

The European Union (EU) is the second largest medical market in the world and imports a large proportion of its medical products from China and Taiwan. In Germany, for example, the share for certain products such as respiratory masks is up to 90 percent, according to the Kiel Institute for the World Economy (IfW).

*Safety and quality in almost all areas of business and life: That’s what TÜV Rheinland stands for. The company has been active for more than 150 years and is one of the world’s leading testing service providers. TÜV Rheinland has more than 20,000 employees in over 50 countries and generates annual sales of around 2.3 billion euros. TÜV Rheinland’s highly qualified experts test technical systems and products around the globe, accompany innovations in technology and business, train people in numerous professions and certify management systems according to international standards. In this way, the independent experts ensure trust along global flows of goods and value chains. Since 2006, TÜV Rheinland has been a member of the United Nations Global Compact for more sustainability and against corruption. Website:* [*www.tuv.com*](http://www.tuv.com)

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