

Press Release

DEKRA entities in the Netherlands and Spain

DEKRA tests and assesses mechanical ventilators during the COVID-19 pandemic

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- Various prototypes of mechanical ventilators are being tested and assessed to assure they meet the safety requirements when used with patients at hospitals
- DEKRA entities in the Netherlands and Spain are able to test and assess the medical equipment according to the accelerated processes exceptionally defined by the European Commission and by the local governmental authorities.

COVID-19 is causing respiratory problems for a multitude of patients and is directly affecting hospitals, especially Intensive Care Units (ICU), where in many cases there are not enough mechanical ventilators to help patients to breathe. DEKRA laboratories in Arnhem (the Netherlands) and Malaga (Spain) are working on various projects of ventilator system manufactures. As these medical devices need to be assessed to assure its safety, the DEKRA teams are working hard to get it ready in the officially agreed accelerated timelines.

At the recommendation of the EU Commission (2020/403) dated March 13, 2020, the market supervisory authorities defined simplified processes for the market entry of medical devices. This accelerated process is designed to allow medical devices, which comply with the minimum basic requirements, to be approved for public use by the market supervisory authorities. The requirements for this accelerated process and minimum basic requirements are defined by the local governmental authorities. DEKRA is now involved in various assessments of ventilator systems to help during the coronavirus pandemic.

DEKRA in the Netherlands is able to test and review the medical equipment according to these accelerated processes as a Notified Body and as defined by the local governmental authorities. DEKRA in Spain is a laboratory authorized by the Spanish Agency of Medicines and Medical Devices (AEMPS), which is the Notified Body in Spain for electromedical equipment. The laboratory confirms the compliance with the testing principles of the relevant standards via a test report.

The medical Notified Body part of DEKRA in Arnhem recently assessed the [DemcAir](#) via this simplified procedure. Demcon is specialized in the production of ventilation modules, which includes the hearth of the ventilator system – the blower. Demcon's expertise relating to ventilation modules and system engineering resulted in the Dutch government placing an order in March for five hundred

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complete ventilation systems. This ventilator is a more simplified model that connects to a laptop will be used during the COVID-19 pandemic only. DEKRA has reviewed the technical documentation of the ventilation system and the documents are authorized by the Dutch Ministry of Health, Welfare and Sports which also has a dedicated clinical team that coordinates the testing of medical equipment in the hospitals.

In Malaga, the test laboratory of DEKRA conducted the testing for 'Andalusia Breath' project, an initiative born from a ventilator prototype designed by a doctor some years ago. Due to the high demand for respiratory systems at hospitals during coronavirus pandemic, he realized his model could be helpful. Together with a team of specialists from the Biomedical Research Institute from Malaga (IBIMA) and Malaga university, and with the collaboration of Regional Government (Junta de Andalucía), they created a ventilator completely useful and functional to assist patients with respiratory problems, although the purpose of 'Andalusia Breath' ventilator is to be used just in emergencies when there are not any other complex ventilators available.

Electromagnetic compatibility (EMC), as well as functional and electrical safety tests of this ventilator, were performed by a team from the DEKRA laboratory in Malaga. The team managed to finish the testing period in one week, reducing considerably the duration of the procedure, which usually takes over a month. The Spanish Agency of Medicines and Medical Devices, the authorized body in Spain, finally approved and certified 'Andalusia Breath' ventilator on April 11. Manufacturing of ventilators has already started. 'Andalusia Breath' project is an example of successful cooperation among different partners on health and safety.

Both the teams in Arnhem and Malaga are currently involved in multiple assessment procedures for ventilators especially designed for the use in the coronavirus pandemic. Next to medical devices, there is also an accelerated process for Personal Protective Equipment like respiratory masks for the coronavirus pandemic. [DEKRA in Essen](#), Germany, is one of the suitable laboratories for these types of tests.

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About DEKRA

DEKRA has been active in the field of safety for more than 90 years. Founded in 1925 in Berlin as Deutscher Kraftfahrzeug-Überwachungs-Verein e.V., it is today one of the world's leading expert organizations. DEKRA SE is a subsidiary of DEKRA e.V. and manages the Group's operating business. In 2019, DEKRA generated sales totaling 3.4 billion euros. The company currently employs almost 44,000 people in approximately 60 countries on all six continents. With qualified and independent expert services, they work for safety on the road, at work and at home. These services range from vehicle inspection and expert appraisals to claims services, industrial and building inspections, safety consultancy, testing and certification of products and systems, as well as training courses and temporary work. The vision for the company's 100th birthday in 2025 is that DEKRA will be the global partner for a safe world.