

## PRESS RELEASE

### **em-tec GmbH develops a new single-use ultrasonic perfusion sensor on behalf of Swiss medical device expert FUMEDICA AG**

*With this new ultrasonic flow measurement system, em-tec certifies itself for the first time as a manufacturer of sterile products in medical technology. The innovative system is exclusively distributed by Fumedica AG.*

Finning, March 2019: The medical technology specialist em-tec GmbH has successfully completed the development, series production and approval phases for the Fumaflow® system.

The tried and tested em-tec technology, which is used for non-invasive coronary flow measuring by means of ultrasound, has been successfully developed to meet the sterilisation requirements of single-use medical equipment. In the future, Fumaflow®, which is used for accurately measuring distal leg perfusion in ECLS, selective brain perfusion in aortic surgery, selective organ perfusion in thoracic abdominal aortic surgery, and selective cardioplegic perfusion, will be distributed worldwide by em-tec GmbH on behalf of Fumedica AG. For the first time, the EC certification [Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) / Devices in Class IIa, IIb or III] is to be extended to include "Sterile Products".

The new Fumaflow® system consists of an ultrasound flow computer and an extremely precise, non-invasive single-use sensor with a standard Luer lock interface (and corresponding sensor adapter), and has been exclusively developed and patented for the Swiss company FUMEDICA AG. FUMEDICA will also coordinate the global distribution of special solutions.

The ultrasonic flow computer has been adapted for FUMEDICA for flow measuring in selective brain perfusion in cases of deep hypothermic circulatory arrest (DHCA), or for accurate flow measuring in visceral or renal perfusion in thoraco-abdominal aortic surgery. Other applications include flow monitoring during selective cardioplegic perfusion, or distal perfusion flow measuring in cardiopulmonary bypasses. Nothing stands in the way of further uses, if the sensor specifications are within the scope of application. The sterile and precise single-use flow sensor is connected to the selective perfusion catheter by means of a standard Luer lock on the interface of the cardioplegic line. This enables selective flow measuring for each perfusion catheter. As usual, the pressure is measured separately using the cardioplegic line, and is represented by the pressure on the tip of the perfusion catheter. For the first time, the combined pressure and flow measurements towards each end organ system are quantitatively correct.

"We are pleased to have received all the necessary certifications after a development period spanning more than two years, so that we can now bring the product onto the market", says Markus Traxler, who became the sole managing director of em-tec GmbH in February 2019. Urs Christen, the founder, owner and managing director of Fumedica AG, agrees.

em-tec was previously managed jointly by Mr Traxler and BlueCap manager Hannspeter Schubert. Innovation should also play a major role in corporate strategy: "We recently gave the go-ahead for the construction of our new head office. A modern office building, covering a surface area of almost 5,000 square metres, and with space for up to 150 employees, is currently being built. The new development centre, where up to 50 developers will work on product innovations for the medical technology sector, in an area covering more than 600 square metres, is of particular importance", explains Mr Traxler.

**FUMEDICA AG at a glance:** Since the 1980s, FUMEDICA AG has been a specialist supplier in the fields of cardiac surgery, vascular surgery, interventional cardiology, anaesthesia and intensive medicine, and offers a wide range of treatment concepts and products. The Swiss company is characterised by innovative in-house developments, reliable therapeutic solutions, professional advice and service, as well as inspiring identification with its products and services. [www.fumedica.ch](http://www.fumedica.ch)

**em-tec GmbH at a glance:** For 30 years, em-tec GmbH's factory in Finning has manufactured innovative and economic products, as well as customised medical technology solutions, and some items which are not for medical use. From the initial idea to marketing, em-tec's vision is to be the ideal partner in all stages of product development and contract manufacturing. The highest demands in terms of certification (ISO 13485) and quality management are fulfilled. The focus is on life support devices, especially in the field of cardiac surgery or cardiac support systems. One of the key competencies lies in the field of non-invasive flow measuring, using the ultrasound transit-time method. Based on this technology, em-tec offers products and components for medical and non-medical use, e.g. for cardiac or vascular surgery, work in the laboratory, bio-processes, or other industrial applications which require flexible tubing. The rapidly-growing business in the medical technology sector belongs to the Munich-based BlueCap Group. [www.em-tec.de](http://www.em-tec.de)

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