# *Our Road from OEM Modules to Full Medical-Grade Devices*

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As most of the readers certainly know, LEANFA is an Italian Company specialized in design and manufacturing of solid-state microwave and radiofrequency amplifiers and generators, now member of the MUEGGE Group for one year.

Our specialty has always been to provide compact generator modules to manufacturers of industrial, scientific and medical devices, with the precise aim of being their trusted technical partners allowing them a quick introduction of innovative technologies in the market. So, during the first years of activity, our team has mainly worked in providing customization engineering support and helping customers with mechanical, electronic and software integration of our generator modules into their systems, progressively more with manufacturers of medical devices.

The characteristics of our solid-state microwave generators that mainly attracted our customers in the medical world have been their accuracy, long-term reliability and performance repeatability, all fundamental characteristics for the compliance of medical devices to the relevant international standards. In particular, all the new medical devices manufacturers in the EU have to comply with the new European MDR (Medical Devices Regulation), mainly aiming at assuring the highest clinical safety while guaranteeing transparency in defining market access rules. From a more technical point of view, the international reference standards for microwave-driven medical devices are mainly EN 60601-1 (basic safety and essential performance), EN 60601-1-2 (EMC requirements), EN 60601-1-8 (alarm systems requirements), EN 60601-2-6 (particular requirements for microwave therapy devices) and IEC 62304 for the software sections. Compliance to the standards is an essential prerequisite to get access to clinical tests and to official validation tests in accredited laboratories, to finally aim at international market certifications as CE and FDA. Almost all the listed reference standards apply also to RF-driven medical devices, our experience has embraced both technologies.

Being initially suppliers of the generator modules, typically in the range of few tens of Watts to 250W, our involvement has been focused on technical documental support and on providing technical know-how on radiofrequency and microwaves to get the maximum benefit from the clinical procedures. With both technologies the operator aims at quickly heating a pathological tissue to a temperature higher than 60°C to induce *coagulative necrosis* of its cells, while trying to preserve the surrounding healthy tissues. Typically needles or catheters are introduced into the target tissue to let the RF or microwave energy be effectively transferred to the target cells.

Heating induced by a RF generator is linked to the Joule effect associated with the RF current flow, in a procedure typically supported by impedance control algorithms that avoid dehydrating the tissue too quickly before the target reaches the desired temperature and final necrosis. A MW generator transfers electromagnetic energy to the polar molecules of the tissue (e.g., water), progressively raising their temperature, in procedures that are typically supported by temperature control algorithms and that are less susceptible to drying phenomena and allow larger volumes to be heated uniformly in less time.

Starting from 2019, our team has been asked not only to provide the core generator modules, but also to develop full medical-grade devices including chassis, hardware, software and all the accompanying technical documentation essential for the clinical tests and the final certification. This new approach has been real impacting at the beginning, but the flexibility of our young team of R&D engineers, the top performances of our solid-state generators and very focused consultancy received by highly skilled biomedical engineers have all contributed to build remarkable success

stories in the fields of cancer therapy and treatment of chronic pain.

After four years working with medical-grade devices, our team has gained during 2023 two memorable milestones for the LEANFA history: the first official FDA certification (through the so called 510k process) for an RF-driven multi-probe generator and the ISO 13485 quality certification, both precious excellence seals that give us even more energy to progressively expand the scope of our solid-state microwave technology towards a better life, worldwide.

**About the author**

**Marco Fiore** received his M. Sc. degree in electronics engineering at Politecnico di Bari, Italy. He has worked for more than 15 years in the field of digital telecommunications and broadcasting, from design tasks to operational management, always dedicated to implement deep interaction between high-frequency power electronics and programmable digital devices. He is co-founder of LEANFA in 2014, fully devoted to foster new business opportunities in Industrial, Scientific and Medical fields by means of innovative solid-state generators powered by distributed software applications.

# *Current Research Activities on Microwave Technologies at the Universidad Politécnica de Cartagena*

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After twenty-five years at the Universidad Politécnica de Cartagena (UPCT), the research group "Electromagnetismo y Materia" (GEM) has consolidated its structure with four professors, one senior lecturer, one lecturer, and three assistant researchers. It has also continued to receive funding for microwave and electromagnetic technology-related projects from national, regional, and European programs. While it's challenging to categorize everything we do, over the past few years, we have mostly worked with permittivity measurement, microwave filter design, microwave cloth dryers, calibration techniques, microwave-assisted waste recycling, radiomap generation, microwave sterilization, and axion search measurements using microwave haloscopes.

**Methods for measuring permittivity**

An original approach for characterizing the permittivity of liquids and granular materials in relation to temperature, density, and moisture content changes based on the Dielectric Kit for Vials from the ITACA Institute at the Universidad Politécnica de Valencia has been developed within the GEM, allowing us to characterize a significant number of materials, including cloth aggregates, cypress and rockrose biomass, coffee, quinoa (**Figure 1**), etc. Furthermore, for materials with non-canonical forms, we have refined our inverse measurement techniques to reduce the uncertainty of sample position within waveguides [1, 2].

**High-power stop-band coaxial filter design**

High-power band-stop coaxial filters offer significant benefits to microwave applicators because they make it possible to add instruments and probes that could be used to enhance or monitor microwave heating applications. As seen in **Figure 2**, the initial use of these filters was the addition of metallic stirrers inside the microwave applicators that did not exhibit any discernible leakage. This