



Safe Medical announces the renewal of its ISO 13485 certification of its production site on an extended perimeter including clean rooms

- ▶ Renewal of certification for 3 years
- ▶ Full in-house production
- ▶ Qualification of 3D additive printing and start of production of first projects

Eragny-sur-Oise, Fleurieux sur l'Arbresle, France, September 22th, 2022 5:45pm CET – Safe Medical , a subsidiary of Safe Group (FR0013467123 – ALSAF), a company specializing in the design, manufacturing and marketing of single-use technologies for spinal surgeries, delivering the safest treatment for spinal fractures urgently treated, announces the renewal of its iso 13485 certification for its industrial production site in Fleurieux sur l'Arbresle.

Safe medical, a subsidiary that manufactures medical devices for Safe Orthopaedics and for third parties, has had its ISO 13485 certification relating to quality management standards to produce medical devices renewed for the next three years.

In addition, one year after the commissioning of the site's clean rooms, the Safe Group has announced the total internalization of the manufacture and packaging of its ready-to-use surgical kits.

Finally, the qualification of 3D metal additive printing, financed by the stimulus plan in 2021, means that the first projects for new-generation medical devices can now be put into production, providing shapes and structures that facilitate bone regrowth, particularly in the case of interbody cages.

" Since the summer of 2020, our Safe Group has been engaged in a production integration process. Manufacturing and innovation in ready-to-use technologies require specific industrial resources and skills that Safe Medical has implemented and qualified over the past two years. We are very proud to announce the renewal of our ISO 13485 certification as well as the expansion of our industrial capabilities with the qualification of additive printing," commented Pierre Dumouchel, Chairman and CEO of the Safe Group. "We are now producing all of our Safe Orthopaedics technologies in-house, halving our manufacturing lead times and improving our gross margin and associated working capital. These new facilities also enable us to offer other Safe Medical customers a very wide range of industrial processes, facilitating the qualification of processes that are increasingly constrained by new European regulatory requirements, as well as savings compared with a multi-supplier supply chain. Our double-digit growth confirms this group strategy "



About Safe Group

Safe Group is a French medical technology group that brings together Safe Orthopaedics, a pioneer in ready-to-use technologies for spine pathologies, and Safe Medical (formerly LCI Medical), a medical device subcontractor for orthopaedic surgery. The group employs approximately 150 people.

Safe Orthopaedics develops and manufactures kits combining sterile implants and single-use instruments, available at any time to the surgeon. These technologies are part of a minimally invasive approach aimed at reducing the risks of contamination and infection, in the interest of the patient and with a positive impact on hospitalization times and costs. Protected by 18 patent families, SteriSpine™ kits are CE marked and FDA approved. Safe Orthopaedics is headquartered in the Paris region (95610 Eragny-sur-Oise) and has subsidiaries in the United Kingdom, Germany, the United States and the Lyon region (Fleurieux-sur-l'Arbresle).

For more information: www.safeorthopaedics.com

Safe Medical produces implantable medical devices and ready-to-use instruments. It has an innovation center and two production sites in France (Fleurieux-sur-l'Arbresle, 69210) and in Tunisia, offering numerous industrial services: design, industrialization, machining, finishing and sterile packaging. Supported by the French stimulus plan in 2020, the company invests in additive printing and will be operational in 2022 on this new technology.

For more information: www.safemedical.fr

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