

PHARMANUTRA S.P.A. OBTAINS ISO 13485 CERTIFICATION
THE CERTIFICATION REPRESENTS A STRATEGIC ASSET TO ENHANCE SAFETY STANDARDS
ACROSS THE ENTIRE PRODUCT LIFECYCLE, IN LINE WITH THE MOST DEMANDING
INTERNATIONAL CONTROL SYSTEMS

Pisa, 28 January 2026 – [Pharmanutra S.p.A.](#) (MTA; Ticker: PHN), a company specialized in mineral-based nutritional supplements and medical devices for muscles and joints, announces that it has **officially obtained ISO 13485 certification**, the international standard that defines specific requirements for a **Quality Management System (QMS) in the regulated medical devices sector**, within a global context of increasing convergence between para-pharmaceutical products and advanced medical technologies.

The achievement of this certification reflects a rigorous approach to risk management throughout the entire product lifecycle, unequivocally certifying **Pharmanutra's commitment to ensuring the highest standards of safety, efficacy, and quality** in the design, manufacturing, and distribution of its medical devices and related services worldwide. The ISO 13485 certification further confirms the Group's full compliance with applicable regulatory requirements, as well as its ongoing focus on reliability and its ability to meet and exceed the expectations of customers, international partners, and stakeholders at large.

Compliance with this standard represents a highly strategic milestone for the Group at an international level, as it facilitates access to foreign markets by reducing technical and regulatory barriers, particularly in view of the upcoming regulatory developments in the United States. As of 2 February 2026, the U.S. Food and Drug Administration (FDA) will harmonize its requirements for medical devices (Quality Management System Regulation – QMSR) with ISO 13485:2016.

The ISO 13485 certification will also support the development of partnerships with leading healthcare organizations, as many supply agreements and international tenders require this certification as a mandatory prerequisite. At the same time, it enables the integration of traditional pharmaceutical regulatory frameworks and processes with a dedicated structure tailored to the technological and mechanical components of modern healthcare systems.

Germano Tarantino, Chief Scientific Officer of Pharmanutra S.p.A., comments: *"For Pharmanutra, attention to product quality and the utmost guarantee of consumer safety have always been priority and non-negotiable principles. This new certification, which adds to the other quality certifications we already have in*

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place, is certainly among the most rigorous globally and confirms that our medical devices comply with the highest standards of quality and safety. This added value will represent a further competitive advantage for the Group, also in terms of winning new supply contracts in the healthcare sector and participating in international tenders where ISO 13485 certification is a mandatory requirement.'

Pharmanutra S.p.A.

Founded in 2003 in Pisa by Andrea and Roberto Lacorte, Pharmanutra is the holding company of an international Group engaged in the research, development, and commercialization of nutritional supplements, medical devices, and patented raw materials. A leader in iron-based supplements through its Sucrosomial® Technology (SiderAL® and Apportal®), and an emerging player in medical devices for mobility (Cetilar®), the Group internally manages the entire value chain and holds a solid portfolio of patents, brands, and clinical evidence.

Pharmanutra operates in over 80 countries, with subsidiaries in the USA and Spain, and also includes Akern S.r.l. (bioimpedance analysis) and Athletica Cetilar S.r.l. (sports medicine).

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