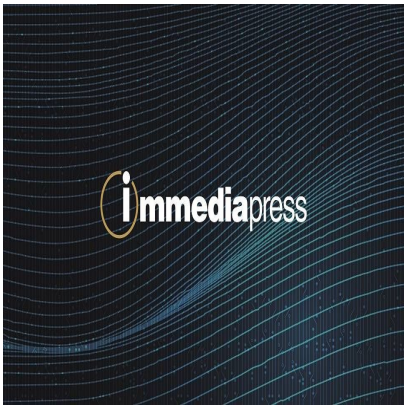

AphranelÂ® MagiCCrystal CaHA Filler Achieves EU MDR Certification as a Premium Regenerative Injectable

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

SHANGHAI, May 28, 2026 /PRNewswire/ â?? Moyom Biotechnology announced that its premium regenerative aesthetics product, AphranelÂ® MagiCCrystal CaHA Filler officially achieved European Union Medical Device Regulation (EU MDR) certification on May 18, 2026, under the registered name â??Calcium Hydroxylapatite (CaHA) Microsphere Injectable Facial Fillerâ?•.

AphranelÂ® is among the first regenerative CaHA injectable fillers from the Asia-Pacific region to achieve certification directly under the EU MDR framework, and is premium regenerative CaHA filler from the Asia-Pacific region directly certified under EU MDR.

The certification confirms that the product complies with the European Unionâ??s stringent regulatory requirements across quality management, clinical evaluation, manufacturing standards, safety, traceability, and post-market surveillance.

Implemented in May 2021, the EU Medical Device Regulation (MDR) replaced the previous Medical Device Directive (MDD) and introduced significantly stricter requirements for medical device compliance throughout the European market. Under MDR transition regulations, medical devices without MDR certification after December 31, 2027, will no longer be permitted to remain on the EU market.

The certification process lasted 2 years and 7 months under the MDR Class III pathway for high-risk absorbable implantable medical devices, without equivalence routes or exemptions.

To support the certification, Moyom Biotechnology completed the EU MDR conformity assessment process with BSI, a UK-based Notified Body and the worldâ??s first MDR-designated organization.

During Aphranelâ??s early global expansion, the company was once advised to adopt a European brand identity for international markets.

However, Aphranelâ??s founder believed otherwise:

â??We believe a global regenerative aesthetics brand can originate from China.â?• That position has continued to shape the companyâ??s long-term international strategy.

In the field of regenerative medical aesthetics, Calcium Hydroxylapatite (CaHA) technologies have historically been led by a limited number of international manufacturers, with few major technological advances over the past decade.

Aphranel has pursued a different direction through proprietary R&D focused on fully biodegradable CaHA materials, advancing microsphere structural design, degradation pathway validation, and manufacturing optimization.

Aphranel has maintained a product-led, long-term development strategy. Alongside Chinaâ??s first Class III medical device approval for an original CaHA microsphere injectable facial filler, the company has continued refining its biomaterial formulation design and conducting long-term safety studies, including clinical follow-up extending up to 39 months.

The product instructions also specify complete in vivo biodegradation, validated through clinical and regulatory compliance standards.

Aphranelâ??s CaHA injectable facial filler is formulated with 30% CaHA microspheres and 70% CMC gel carrier. The material is designed to provide immediate structural support and stimulate collagen regeneration through biostimulatory mechanisms.

Its core technologies include the patented ACD-MTÂ® CaHA microsphere structure and PCD-ETTÂ® gel technology. The CaHA microspheres measure approximately 30â??35 Î¼m and feature a raspberry-shaped porous structure designed to support tissue integration and collagen regeneration. With a Gâ?? value of approximately 5500 Pa, the material provides injection stability while maintaining gradual biodegradation.

The material contains no residual chemical cross-linking agents. As the material gradually biodegrades, released calcium ions are naturally metabolized within the body, contributing to long-term tissue compatibility.

In Chinaâ??s premium medical aesthetics market, Aphranel is positioned as a high-end regenerative injectable product, with a recommended retail price of RMB 12,800 per 0.5 mL syringe.

Aphranel has also introduced the concept of â??The Poetics of Time,â?• reflecting its focus on regenerative aesthetics, gradual improvement, and long-term structural results.

In January 2026, Aphranel presented at IMCAS Paris 2026, one of the worldâ??s leading medical aesthetics congresses, broadening its international academic and professional presence.

For Moyom Biotechnology, the MDR certification marks a contribution to the global development of regenerative aesthetics through biomaterial innovation, clinical research, and international collaboration.

View original content:https://www.prnewswire.com/news-releases/aphranel-magiccrystal-caha-filler-achieves-eu-mdr-certification-as-a-premium-regenerative-injectable-302784208.html

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Categoria

1. Comunicati

Tag

1. ImmediaPress

Data di creazione
Maggio 28, 2026
Autore
redazione