

Press Release

PALACOS bone cements with gentamicin receive MDR approval

Heraeus Medical announces that their antibiotic containing PALACOS bone cements have received MDR (Medical Device Regulation) approval. These include the products PALACOS® R+G, PALACOS® MV+G, PALACOS® LV+G and PALACOS® fast R+G.

Receiving the certificate confirms the quality and safety of our products as well as our high production standards. "We are pleased to continue to provide our customers with our high-quality, proven products, thereby ensuring the best possible patient care." said Nicole Petermann, President of Heraeus Medical.

"We are proud that the majority of our products have now been submitted to the Notified Body and expect to have all products approved under the MDR requirements in 2023."

PALACOS® R+G is the world's first antibiotic-containing bone cement in arthroplasty and a leader in clinical evidence.¹ For more than 50 years, this bone cement stands for unique product quality that contributes to a higher quality of life for patients.

Heraeus Medical has also recently been certified according to MDR. The certificate confirms that the company comprehensively fulfills all requirements of the MDR regarding the QM system, processes, and production standards. The MDR (Medical Device Regulation / European Medical Device Regulation) replaces the existing medical device directives.

1. Pilz V, Hanstein T. A Literature Review of the Clinical Evidence Situation of Bone Cements. Research & Reviews: Journal of Medical and Health Sciences 2018; 7(1): 31–36.

About Heraeus

The Heraeus Group is a broadly diversified and globally leading family-owned technology company, headquartered in Hanau, Germany. The company's roots go back to a family pharmacy started in 1660. Today, the Heraeus Group includes businesses in the environmental, electronics, health and industrial applications sectors. Customers benefit from innovative technologies and solutions based on broad materials expertise and technological leadership. In the 2021 financial year, the FORTUNE Global 500 listed group generated revenues of €29.5 billion (US\$34.9 billion*) with approximately 16,200 employees in 40 countries. Heraeus is one of the top 10 family-owned companies in Germany and holds a leading position in its global markets.

About Heraeus GBU

Heraeus Medical is a leader in the field of bone cements and biomaterials for surgical orthopedics and trauma surgery. In this way, the company makes a decisive contribution to supporting the surgeon and the surgical team to improving the surgical outcome. In the field of biomaterials, Heraeus Medical focuses on products for use in bone and joint surgery. The core product PALACOS® is considered the gold standard among bone cements and has proven itself in clinical use for over 60 years and more than 34 million procedures worldwide.

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