

14 July 2025

Osteopore gains Swiss market approval

Highlights

- Osteopore secures market approval in Switzerland under the European Union (EU) Medical Device Regulation (MDR).
- The approval follows Osteopore's successful transition to MDR in 2023, its partnership with Zimmer Biomet (NYSE and SIX: ZBH) in 2024, and recent European approvals for its custom-made implants used in neurosurgery and orthopaedic surgery.
- The approval of Osteopore's off-the-shelf and custom-made implants completes the product portfolio, strengthening support for market entry into Switzerland and across Europe.

Australian-Singaporean regenerative medicine company **Osteopore Limited** (ASX: **OSX**; **Osteopore** or **the Company**) – a global leader in 3D-printed biomimetic and bioresorbable implants – is delighted to announce that it has secured market approval for Switzerland.

Switzerland participates in the EU's single market through a series of bilateral treaties and agreements, despite not being a member state.

Prior to the EU's new MDR taking effect on 26 May 2021, the Mutual Recognition Agreement (MRA) enabled the trade of CE-marked medical device products between the EU and Switzerland.

In the absence of a renewed MRA covering CE-marked medical devices under the MDR, Switzerland was classified as a "third country" similar to the UK post-Brexit. As a result, Switzerland implemented its regulations for all CE-marked medical devices.

Following Osteopore's successful transition to the MDR in 2023,¹ the Company struck an exclusive agreement with Zimmer Biomet (NYSE and SIX: ZBH), to distribute its MDR-approved craniofacial products in Europe, the Middle East and Africa (EMEA), Asia Pacific (APAC), Australia and New Zealand. Subsequently, Osteopore secured additional market approvals for its custom-made implants used in neurosurgery and orthopaedic surgery².

Osteopore's additional custom-made neurosurgery implants, together with its off-the-shelf products, provide Zimmer Biomet with a complete suite of products to approach the Swiss and European markets.

The cranial implant market in Europe is expected to reach USD527.6 million by 2027, the largest product segment being customised implants.³

Commenting on gaining market approval in Switzerland, CEO Dr Yujing Lim said:

"We are delighted to be in the position to support a coordinated approach to the European market, specifically Switzerland, with Zimmer Biomet.

"Our team of regulatory professionals have been working hard to provide us with market authorisation, and we are grateful for their leadership and support," said Dr Lim.

ENDS

This announcement has been authorised for release to the ASX by the Board of Osteopore Limited.

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¹ ASX announcement "OSX Successfully transitions to EU Medical Device Regulation", 27 April 2023.

² ASX announcement "Osteopore secures EU market approvals for custom implants", 9 April 2025.

³ <https://www.grandviewresearch.com/horizon/outlook/cranial-implants-market/europe>

About Osteopore Limited

Osteopore Ltd. is a global medical technology company founded in Singapore and listed in Australia that commercialises products designed to enable natural bone healing across multiple therapeutic areas. Osteopore's patented technology fabricates specific micro-structured scaffolds for bone regeneration through 3D printing and bioresorbable material.

Osteopore's patent-protected scaffolds are manufactured using a proprietary manufacturing technique with a polymer that naturally dissolves over time to only allow natural and healthy bone tissue, significantly reducing the post-surgery complications commonly associated with permanent bone implants. Our 3D printing technology is unique to Osteopore.

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Some of the statements appearing in this announcement may be similar to forward-looking statements. You should be aware that such statements are only predictions and are subject to inherent risks and uncertainties. Those risks and uncertainties include factors and risks specific to the industries in which the Company operates and proposes to operate as well as general economic conditions, prevailing exchange rates and interest rates and conditions in the financial markets, among other things.

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