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Boule receives CE mark according to IVDR Class B for two product lines

Boule Medical AB has reached another important milestone in its preventive and diligent work in meeting the new and increased regulatory requirements for in vitro diagnostics. Boule has received CE mark according to IVDR class B for two of its product lines, Medonic M32 and Swelab Alfa Plus.

IVDR is the EU's new guiding regulation that specifies the safety, integrity and quality requirements for all medical devices that perform an in vitro diagnostic function. The transition from IVDD to IVDR includes a new risk-based classification system that ranks from class A (lowest risk) to class D (highest risk). Class A products are based on self-certification. Class B requires a complete review by a notified body.

Boule's instruments belong to Class B, for which the IVDR comes into effect on May 26, 2027. Taking the quality work one step further, two of the company's product lines, Medonic M32 and Swelab Alfa Plus, were certified already during the fall of 2022. The evaluation and certification for the upcoming higher requirements was carried out by the BSI Group.

"We are very pleased to have already achieved the higher level of quality for our product lines Medonic M32 and Swelab Alfa Plus. We are now members of a globally small and honorable group of medtech companies that have succeeded with this at such an early stage. The certification is proof of what we can achieve with our dedicated quality work and of our desire and commitment to be at the forefront of patient safety. The work to achieve the higher level of quality already now is also important for future product launches," explains CEO and Group President Jesper Söderqvist.

For Class A products, the new IVDR regulations came into effect on May 26, 2022. Boule's work to ensure that the company's Class A products met the new requirements was successfully completed earlier in the spring. Earlier this year, a renewed IS013485 IVDR certificate was also obtained for Boule Medical AB's Quality Management System (QMS), which was another important milestone towards the company's IVDR compliance.

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About Boule Diagnostics AB (publ)

Boule Diagnostics AB is a global diagnostics company that develops, manufactures, and markets instruments and consumable products for blood diagnostics. The company serves hospitals, clinics, laboratories, and companies within blood diagnostics, in both human and veterinary hematology. The company operates via subsidiaries in Sweden, the USA, Mexico, and Russia. The company's products are sold globally, primarily through distributors supported by Boule's own local sales and support personnel. Boule Diagnostics' shares are listed on Nasdaq Stockholm since 2011. www.boule.com

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