CellaVision receives CE marking according to IVDR Class C for CellaVision® Bone Marrow Aspirate Application

Today, CellaVision has reached another important milestone and announces that its new CellaVision Bone Marrow Aspirate (BMA) Application has received CE marking approval as a Class C product under the European Union In Vitro Diagnostic Regulation (EU IVDR).

IVDR is the EU's governing regulation that sets high requirements for the safety, performance, and quality of in vitro diagnostic devices. The IVDR device classification ranks from class A (lowest risk) to class D (highest risk). Class A products are based on self-certification, whereas Class B-D require a complete review by a notified body. Devices such as the CellaVision BMA Application which are intended to be used for screening, diagnosis, or staging of cancer should be classified as Class C devices.

The CE-marked CellaVision BMA Application offers laboratories a trusted and advanced solution for automating, standardizing, and simplifying the morphological examination of bone marrow aspirate.

The CellaVision BMA Application runs on the CellaVision DC-1 instrument using a 100X objective. The CellaVision DC-1 is a compact, high-quality image analysis instrument that has been CE marked and commercially available since 2019. It is supplied with the CellaVision Peripheral Blood Application as a standard feature.

By adding the CellaVision BMA Application to the CellaVision DC-1 instrument, laboratories can analyze and review both bone marrow and peripheral blood samples side by side. This supports more comprehensive assessments when abnormalities are detected in the blood or when a diagnosis with bone marrow involvement is suspected.

Bone marrow cytology, the examination of bone marrow cells under a microscope, remains a recommended method by the World Health Organization and other professional bodies for diagnosing many blood and bone marrow disorders. Malignant hematological diseases represent a significant share of all diagnosed cancer types and are major contributors to the cancer burden of the global population. Examination of the bone marrow aspirate is central to establishing diagnoses for these and other hematologic conditions. Traditional manual microscopic analysis remains a resource-intensive and time-consuming process. The CellaVision BMA Application offers a traceable, intuitive, and collaborative workflow enabling bone marrow experts to review cases efficiently and consistently, thereby reducing their overall workload.

The CellaVision BMA Application consists of the CellaVision BMA Analyzer Software and the CellaVision BMA Review Software. The advanced CellaVision BMA Analyzer Software automatically locates, pre-classifies, and stores bone marrow aspirate cells based on morphology using advanced AI-driven technology. Paired with the CellaVision BMA Review Software, users can securely access cell images and verify pre-classification results from any location, at any time.

"The certification demonstrates our dedicated quality efforts, as well as our ambition and commitment to be at the forefront of streamlining bone marrow morphology examination. Furthermore, this accomplishment exerts yet another testimony in our relentless effort to digitalize

morphological cell analysis across hematology laboratories worldwide", says Simon Østergaard, CEO at CellaVision.

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About Us

CellaVision is a global medical technology company that develops and sells its own leading systems for routine analysis of blood and other body fluids in health care services. These analyses play a vital role in swift and accurate disease diagnoses, particularly in cases of infections and serious cancer diseases. The products replace manual laboratory work, and secure and support effective workflows and skills development within and between hospitals. The company has leading-edge expertise in sample preparation, image analysis, artificial intelligence and automated microscopy. Sales are via global partners with support from the parent company in Lund and by the company´s 12 local market support organizations covering more than 40 countries. In 2024, sales were SEK 723 million and the company's growth target is 15% per year over an economic cycle. CellaVision's registered office is in Lund, Sweden. The share is listed on the Nasdaq Stockholm, Mid Cap list. Read more at www.cellavision.com

Attachments

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