BiBBInstruments AB
Press release, Feb 7, 2024

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BiBB Receives European CE Mark Approval According to MDR for the Entire EndoDrill Product Family

The cancer diagnostics company BiBBInstruments AB ("BiBB" or the "Company"), which has developed the world's first electric-driven endoscopic biopsy instrument, announces that the Company has received CE certification for EndoDrill® in accordance with MDR. The market approval allows EndoDrill® to be introduced in Europe for all three market segments, i.e. for sampling of the gastrointestinal tract, lungs, and bladder. With the CE mark in place, the Company plans to launch EndoDrill® GI in 2024 to targeted customers. Several clinical market studies are also planned to highlight the benefits of the EndoDrill® technology. BiBB received 510(k) clearance from the US FDA for EndoDrill® GI in 2023 and in January 2024, the first clinical procedures with EndoDrill® GI in the US were successfully completed at UC Davis Health, Sacramento, California.

BiBB's notified body has granted a CE certificate in accordance with MDR, the new EU regulation for medical devices, for the Company's three variants in the EndoDrill® product family. The announcement follows a detailed review process that has proven the high standard of BiBB's products and quality system. The CE mark approval means that all clinical indications applied for EndoDrill®, without exception, are now market approved in Europe. BiBB's first product, EndoDrill® GI, gained a lot of interest when it was presented for the first time at the Nordic EUS Oslo Congress in December. Recently, Dr. Antonio Mendoza Ladd, Medical Director of Endoscopy at UC Davis Health, conducted the first clinical cases of the EndoDrill® GI in the US and his spontaneous comment was: "*This device will be a game changer in my opinion!*". The Company will announce further details on expanded clinical marketing acitivites and launch preparations at a later date.

"This is fantastic news for BiBB ahead of our planned market introduction in Europe. Obtaining CE certification according to MDR for all products in the EndoDrill® family is a great achievement by the BiBB team and a strategically very important milestone. BiBB now have the right to market and sell new electric EndoDrill® on the European market. EndoDrill® has thus become the first electric-driven endoscopic biopsy system to be cleared in both the US (FDA 510k) and Europe (CE MDR) within a period of less than a year. The CE approval is an important step towards our vision to advance earlier diagnosis of some of the most serious cancers of the lung, pancreas, stomach, esophagus, liver, lymph nodes, and urinary tract", says Fredrik Lindblad, CEO of BiBB.

About the EU Regulation MDR
The Medical Device Regulation (MDR) is an EU regulation (2017/745) that ensures the safety and performance of medical devices. The aim is to improve patient safety through stricter methods of assessment and monitoring on the market. The regulation updates the rules on which medical devices may be on the market, as well as how to provide and use these products. It also contains rules for how medical device companies conduct product evaluations within the EU. This ensures that unsafe and non-compliant equipment does not end up on the market.

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This is a translation of the Swedish press release. If there should be any discrepancies, the Swedish language version prevails.

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This disclosure contains information that BiBBInstruments AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, on February 7, 2024.

About BiBB BiBBInstruments AB

The cancer diagnostics company BiBBInstruments AB develops and manufactures EndoDrill®, a patented product line of electric-driven endoscopic biopsy instruments. The EndoDrill® instruments take high-quality tissue samples with high precision with the goal of improving the diagnosis of several serious cancers, such as stomach, pancreas, liver, lung, and bladder. The product portfolio is aimed at the global market for ultrasound-guided endoscopic (EUS/EBUS) biopsy instruments, which constitute the most advanced and fast-growing area of endoscopy. BiBB received 510(k) clearance from the US FDA for the lead product EndoDrill® GI in 2023. At the beginning of 2024, CE marking according to MDR was also obtained for all three product variants: EndoDrill® GI, EndoDrill® EBUS and EndoDrill® URO. Thus EndoDrill® is the first cleared electric endoscopic biopsy system in both the US and Europe. The EndoDrill® system includes sterile disposable biopsy instruments with associated drive system. The company was founded in 2013 by Dr. Charles Walther, cancer researcher at Lund University and senior consultant in clinical pathology at Skåne University Hospital in Lund. BiBBInstruments is based at Medicon Village in Lund and the BiBBInstruments share (ticker: BIBB) is listed on Spotlight Stock Market.