BiBBInstruments AB
Press release, 2023-04-18

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BIBB informs about the status of the CE marking process according to MDR

The cancer diagnostics company BiBBInstruments AB ("BiBB" or the "Company"), which develops and manufactures a new type of electric-driven endoscopic biopsy instrument, EndoDrill®, hereby provides a status update on the CE mark approval process of the product portfolio EndoDrill®. In summary, after discussions with BiBB's notified body, the Company expects a CE certificate according to MDR in approximately 3–6 months. The upcoming CE certificate according to MDR means an extended indication and includes all three instruments in the product family EndoDrill®.

At the turn of the year 2021/2022, BiBB applied for CE certification according to MDR of EndoDrill® to the Company's notified body, i.e., submission of an application for a certificate according to the new EU regulation to be able to market and sell CE-marked EndoDrill® instruments on the European market. The application includes previously CE-marked (according to former directive MDD, expired in August 2022) biopsy instruments for the upper gastrointestinal tract (EndoDrill® GI), and for the lungs (EndoDrill® EBUS), and now also instruments for the urinary tract (EndoDrill® URO).

After a lengthy review process, one issue remains to be addressed to obtain approval. The remark concerns a process in the final stages of manufacturing managed by an external partner. Following discussions between BIBB and the notified body, there is now an agreed plan to close the remaining nonconformity and thereby obtain approval for the EndoDrill® product family. The Company estimates that it will take about 3–6 months until a new CE approval according to MDR can be in place.

CE marking according to MDR will mean that planned clinical activities in Sweden will begin immediately. On March 30, 2023, BiBB announced that it had received market clearance for its most important product variant EndoDrill® GI on the US market. With the obtained FDA 510(k) clearance, BiBB plans to also begin clinical market activities in the US.

About EndoDrill®
EndoDrill® gives endoscopists increased opportunities to take high-quality coherent core biopsies in suspected tumors. An intact tissue sample contains more information, which can be crucial for accurate and complete diagnosis as well as the earliest possible start of treatment. The completed clinical pilot study with EndoDrill® GI (EDMX01) showed one hundred percent diagnostic accuracy when analyzing the samples.

EndoDrill® utilizes a patent-pending electric-driven rotating needle cylinder that provides high-precision tissue samples of higher diagnostic quality than existing manually handled EUS biopsy instruments.

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 such products. It also

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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.

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

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About BiBBInstruments AB

BiBBInstruments AB is a medical device company that develops and markets diagnostic instruments under the brand name EndoDrill® for early detection of cancerous tumors. EndoDrill® is the world's first CE-marked and FDA 510(k) cleared electric-driven endoscopic biopsy instrument. The product is designed to provide larger and more high-quality tissue samples (core biopsies) of suspected tumors than existing products. The product family will include biopsy instruments for many of the most serious cancers, such as stomach, pancreas, liver, lung and bladder cancer. EndoDrill® targets the global market for endoscopic biopsy instruments with a focus on the ultrasound-guided biopsy instruments (EUS-FNA/FNB, EBUS-TBNA) segment, which is the fastest growing area in endoscopy. The company was founded in 2013 by Dr Charles Walther, cancer researcher at Lund University and chief physician in clinical pathology at Skåne University Hospital in Lund.