Press Release
28 February 2024

# Carbiotix achieves IVDR and CE marked status for LinkGut testing kit

**Carbiotix (publ) ("Carbiotix" or the "Company") announces today that the Company has received IVDR (In Vitro Diagnostic Regulation) Class A and CE marked status for its LinkGut microbiome testing kit. This represents a key milestone in the development of the testing kit, fulfilling the requirements of several existing and potential customers, and opens up the LinkGut service to the much larger and faster growing clinical study and research segment of the microbiome sequencing services market.**

**Erik Deaner, CEO of Carbiotix, comments:**
"I am extremely pleased to announce that our LinkGut testing kit has achieved both IVDR Class A and CE marked status for clinical diagnostic applications. Achieving IVDR fundamentally ensures traceability of our microbiome testing kit with the purpose of improving clinical safety. The Class A status is self-certified and refers to devices that represent a low individual and public health risk.

Achieving IVDR status fulfills the requirements of several existing and potential customers and opens the door to the much larger and faster growing clinical study and research segment of the microbiome sequencing services market. This segment represents approximately 90% of the total market, a market currently valued at over 2 billion USD and growing at a CAGR of over 20% (1).

Our intention is now to ramp-up marketing activities to companies interested in microbiome science, Contract Research Organisations (CROs) and others interested in leveraging the key advantages of the LinkGut service. Originally designed for price-sensitive consumer segments, the LinkGut service's affordability, flexibility, and reliability are now set to make it an attractive option for clinical and research applications. Our intention is to continue developing the LinkGut service to make it more assessable for clinical and research applications, thereby also positioning CarbiAXOS as a potential modulator of interest for functional foods, nutraceuticals, cosmetics and pharmaceutical adjuvants."

**Compliance details**
The registration at the Swedish Medical Products Agency is according to Regulation (EU) 2017/745 (MDR) on medical devices, Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices, the Swedish Medical Products Agency's Regulations (HSLF-FS 2021:32) on information and reporting requirements regarding medical devices and/or the Swedish Medical Products Agency's Regulations (LVFS 2001:7) on in vitro diagnostic medical devices.

**Forward-looking statements**
This communication contains forward-looking statements, consisting of subjective assumptions and forecasts for future scenarios. Predictions for the future only apply as of the date they are made and are, by their nature, as is research and development work in the biotechnology segment, associated with risk and uncertainty. With this in mind, the actual outcome may deviate significantly from the scenarios as described in this press release.

*This is information that Carbiotix AB is obliged to make public according to the EU Market Abuse Regulation (MAR). The information was made publicly available by the Company's contact person set out below on 28 February 2024.*

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**Carbiotix AB** (CRBX) (www.carbiotix.com) is an award-winning biotechnology company pioneering microbiome healthcare through a portfolio of prebiotic modulators and diagnostic testing services.