MedMira provides an update on the new In Vitro Diagnostic Medical Devices Regulation (IVDR) in the European Market

Halifax, Nova Scotia, 27 May, 2022 – Today, MedMira Inc. (MedMira) (TSXV: MIR) provides an update on its regulatory progress in Europe and any market accepting the CE mark. MedMira has received the CE mark for three products in 2022 and has four additional applications currently pending with the regulatory body. As of today, the Company has been informed that all applications have been accepted and will be forwarded to the Competent Authority for final CE marking. The Company anticipates the respective decisions and CE marks within the coming weeks.

With these steps, the Company has completed its application prior to the change from the In Vitro Diagnostic Medical Devices [98/79/EC: IVD] to the new In Vitro Diagnostic Medical Devices Regulation [EU 2017/746: IVDR] which was set for the 26th of May 2022. EU 2017/746: IVDR is expected to regulate around 80-90% of all In Vitro Diagnostic devices currently in the European market and introduces new scrutiny on in-vitro devices by requiring more rigorous clinical evaluations and through conformity assessments performed by a designated Notified Body.

“The new IVDR regulations are going to have a significant impact on the overall market in terms of regulatory approval. It will be more challenging to achieve an approval and manufacturers will have to show more to get access to the CE market. In short; the entry barriers will be higher, and the quality of the products and the manufacturer will be at the focus of the regulatory bodies. This is going to change the competitive landscape in our favour and we are delighted to have all our current and pending products ready for this change,” said Hermes Chan, CEO of MedMira Inc.

Since the IVDR does not have provisions for grandfathering in-vitro devices, all previously approved in-vitro devices must be re-certified per the new requirements. EU 2017/746: IVDR has no short-term impact on MedMira’s REVEALCOVID-19® and VYRA™ product lines since the Declaration of Conformities for these products are dated before the 26 May 2022 DoA.

The long-term impact of EU 2017/746: IVDR on MedMira’s products including the REVEALCOVID-19®and VYRA™ product lines is also minimal. Rigorous testing performed on all their products, along with compliance to global standards such as MDSAP enable MedMira’s products to stand out amongst their competitors in the European market. Thus, allowing MedMira to quickly transition their in-vitro devices to comply with IVDR with relative ease. Additional information regarding the transition plans will be provided in due course.

Next Update:

A next update will be provided on the 3rd of June 2022.

About MedMira

MedMira is a leading developer and manufacturer of Rapid Vertical Flow® diagnostics. The Company’s tests provide hospitals, labs, clinics and individuals with instant disease diagnosis, such as HIV, Syphilis, Hepatitis, and SARS-CoV-2, in just three easy steps. The Company’s tests are sold globally under the REVEAL®, REVEALCOVID-19®, Multiplo® and Miriad® brands. Based on its patented Rapid Vertical Flow® Technology, MedMira’s rapid HIV test is the only one in the world to achieve regulatory approvals in Canada, the United States, China and the European Union. MedMira’s corporate offices and manufacturing facilities are located in Halifax, Nova Scotia, Canada. For more information visit medmira.com. Follow us on Twitter and LinkedIn.

This news release contains forward-looking statements, which involve risk and uncertainties and reflect the Company’s current expectation regarding future events, including statements regarding possible

regulatory approval, product launch, future growth, and new business opportunities. Actual events could materially differ from those projected herein and depend on a number of factors including, but not limited to, changing market conditions, successful and timely completion of clinical studies, uncertainties related to the regulatory approval process, establishment of corporate alliances and other risks detailed from time to time in the company quarterly filings.

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MedMira Contact
Markus Meile
Chief Financial Officer
MedMira Inc.
ir@medmira.com