

HERABEAT RECEIVES UPGRADED TGA REGULATORY CLASSIFICATION

Highlights:

- HeraMED has received an upgraded Class IIb regulatory classification from the TGA
- HeraBEAT is now the only remote home-use fetal heart rate monitor approved for use for the Australian market
- This approval uniquely positions the HeraBEAT device in the Australian market potentially providing significant commercial opportunity for HeraMED
- HeraBEAT has regulatory approvals in key markets and is both FDA and CE cleared.

HeraMED Limited (ASX: HMD) ("HeraMED" or the "Company"), a medical data and technology company pioneering digital maternity care, is delighted to announce it has received its new Class IIb regulatory classification from the TGA for its market leading, and proprietary, HeraBEAT fetal heart rate monitor.

In July 2022, the TGA began a review of the benefits and risks associated with home-use consumer fetal heart monitors (dopplers) in the Australian market. The result of this review led to the TGA making the decision, in September 2024, to cancel all home-use fetal dopplers supplied in Australia. As part of this decision, HeraBEAT was required to reclassify to a higher class of regulatory classification with its Class IIa approval also cancelled.

HeraBEAT has now received its upgraded Class IIb classification from the TGA and is currently the only remote home-use fetal heart rate monitor approved for use for the Australian market. This approval now uniquely positions the HeraBEAT device, in the Australian market, potentially providing significant commercial opportunity for HeraMED. The HeraBEAT was able to meet the criteria of higher classification as the device, as use of the device and the data generated, forms part of a clinically supervised care plan.

HeraMED CEO Anoushka Gungadin said, "We are delighted with this outcome. The decision by the TGA to remove the use of consumer fetal dopplers from the Australian market without clinical oversight was provided was wholeheartedly supported by HeraMED. Since that decision, and the requirement for reclassification of HeraBEAT, we have actively worked on this reclassification with the TGA.

Through this work, we now have an incredibly unique and exciting commercial opportunity for our proprietary HeraBEAT device and the market position that is now open to it. With this market position we intend to accelerate our Australian go to market strategy targeting of large health systems as well as private clinics and begin to build our market presence in the Australia."

The HeraBEAT is a market leading device which forms part of the suite of remote devices used in HeraMED's market leading digital maternal monitoring solution, HeraCARE. HeraCARE is a clinical grade remote monitoring solution for healthcare providers that offer maternity services.

ENDS

This announcement has been authorised by the Chairman and Managing Director & CEO of HeraMED.

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The HeraBEAT hand-held doppler device is intended to detect and monitor foetal and maternal heart rate. The device is intended to be used by trained pregnant women in a home environment as part of their clinically supervised care plan. The device is to be supplied via a relevant trained healthcare professional who can access and interpret the results from the product's dashboard

The HeraBEAT is also FDA and CE cleared.

**About HeraMED Limited (ASX: HMD)**

HeraMED is an innovative medical data and technology company leading the digital transformation of maternity care by revolutionising the prenatal and postpartum experience with its hybrid maternity care platform. HeraMED offers a proprietary platform that utilises hardware and software to reshape the Doctor/Patient relationship using its clinically validated in-home foetal and maternal heart rate monitor, HeraBEAT, cloud computing, artificial intelligence, and big data.

The Company's proprietary offering, HeraCARE, has been engineered to offer a fully integrated maternal health ecosystem designed to deliver better care at a lower cost, ensure expectant mothers are engaged, informed and well-supported, allow healthcare professionals to provide the highest quality care and enable early detection and prevention of potential risks.