ASX ANNOUNCEMENT **29 April 2019**

HeraMED begins FDA approval process for HeraBEAT

- **HeraMED has submitted a 510K application with the US Food and Drug Administration (FDA) for its medical grade foetal heart rate monitor**
- **The Company is seeking FDA approval ahead of US market entry - expected H1 2020**
- **USA represents a large addressable market with ~4 million births per annum**
- **HeraMED to leverage existing in-country relationships with the Mayo Clinic to drive growth following the regulatory approval process**

Medical technology company, **HeraMED Limited** (**ASX:HMD**) ("**HeraMED**" or the "**Company**") is pleased to advise that it has submitted a 510K application to the US Food and Drug Administration (FDA) to seek FDA approval for its medical grade, foetal heart rate monitor, the HeraBEAT.

The US Food and Drug Administration evaluates and approves a wide range of items for medical use, including drugs and medical appliances. Being granted 510K approval would mean that the FDA has deemed the HeraBEAT device safe and effective for its intended use in the United States.

The United States represents a potentially large addressable market for HeraMED, boasting up to circa 4 million births annually. Following the receipt of the FDA regulatory approvals, the Company expects to enter the United States market, which it anticipates to be in the first half of 2020. Once FDA approval has been granted, HeraMED will liaise with its current R&D collaborator the Mayo Clinic, as well as other medical institutions, hospitals and doctors to drive device uptake.

HeraMED CEO and Co-founder Mr David Groberman said: "Submitting the 510K documentation for the HeraBEAT device represents a major milestone for HeraMED. The United States would represent the Company's largest addressable market, should it be granted approval.

"Board and management look forward to updating shareholders on the process as it progresses."

-ENDS-

HeraMED Limited

CEO and Co-Founder
David Groberman
M:+972-52-6991188
E: David@hera-med.com

Company Secretary
Stephen Buckley
T: +61 (0)8 6189 1155
E: stephen@companysecsol.com.au

Released through: Henry Jordan, Six Degrees Investor Relations, +61 431 271 538

About HeraMED Limited (ASX:HMD):

HeraMED Limited is an innovative medical technology company delivering smart pregnancy monitoring solutions for home and professional use. HeraMED provides peace of mind to expecting parents by solving problems associated with the reliability of pre-natal analysis, as well as the cost and shortage in fundamental services through end-to-end medical grade solutions utilising monitoring devices, cloud based platforms and AI capabilities.

HeraMED is commercialising the worlds most advanced, smart medical grade ultrasound monitoring device HeraBEAT. The device has passed multiple clinical trials and secured approval by key regulatory bodies including TGA (Australia), CE (Europe) and AMAR (Israel) for commercial sale.

The Company has partnerships with two leading medical organisations, the Mayo Clinic and TEVA Pharmaceutical Industries Inc. (NYSE: TEVA). HeraMED diversifying its product range and services with the launch of SaaS services and cloud based monitoring systems.