

G Medical Innovations Holdings Ltd ARBN 617 204 743

## **ASX Announcement**

28 November 2017

## G MEDICAL GRANTED TGA APPROVAL & MEDSAFE CERTIFICATION FOR THE 'PRIZMA' MEDICAL SMARTPHONE CASE

 TGA and MEDSAFE certification opens doors for launch and commercialisation in Australia, New Zealand and other territories.

Mobile and e-Health company **G Medical Innovations Holdings Ltd (ASX: GMV)** is pleased to announce it has been granted both Therapeutics Goods Administration (**TGA**) approval, as well as certification by the New Zealand Medicines and Medical Devices Safety Authority (**MEDSAFE**) for its 'PRIZMA' Medical Smartphone Case.

This is yet another significant milestone for the company, whereby the PRIZMA now officially complies with all relevant Australian and New Zealand medical and safety requirements as a Class IIa Medical device. These certifications effectively mean that the PRIZMA can be made available over the counter as a medical device throughout Australia, New Zealand and additional countries accepting TGA and MEDSAFE certifications.

These additional certifications add to the previously granted approvals for the PRIZMA by U.S Food and Drug Administration (FDA) 510(K), as well as the European 'CE' Class IIa approval, effectively opening up the Global Market for the PRIZMA. With these additional certifications in place, the company can now expedite the ongoing commercial discussions with its potential partners on new agreements.

G Medical Innovations offers a suite of consumer and professional clinical-grade products (regulatory approved) that are positioned to streamline healthcare services, improve remote access to medical data, reduce costs, improve quality of care, and make healthcare more personalised and precise.

The PRIZMA Medical Smartphone Case is one of the innovative products on offer from G Medical, which combines everyday technologies with patented wireless medical sensors and service platforms, practically turning consumers smartphones into a mobile medical health monitoring solution.

G Medical also offers a professional real-time patients continuous monitoring solution, the G Medical Patch (GMP). This modular solution measures a wide range of vital signs that are automatically presented in a call centre (IDTF) or hospital settings. The GMP assists in diagnosing patients' complaints and conditions remotely, from pre-hospitalisation, hospitalisation and through post discharge home-based settings.

With similar regulatory approvals for G Medical's Patch (part of Vital Signs Monitoring System) in the final stages of the process for U.S., Europe and China, the Company looks forward to providing additional business development and regulatory approval updates to shareholders as they unfold.

**Commenting on the Approvals, G Medical CEO Dr. Yacov Geva, said:** "Being granted TGA and MEDSAFE certification allows, in particularly for our Australian shareholders, to fully appreciate the tremendous opportunity at hand for our Company, in providing necessary and unmet medically graded solutions for the monitoring, management and collection of an enormous pool of data for chronic illnesses; as well as providing disruptive and highly cost effective and scalable solutions for the greater healthcare and hospital ecosystems worldwide".





**Ends** 

Corporate Advisors
Otsana Capital
108 Outram Street
West Perth WA 6005
Telephone: +61 8 9486 7244

www.otsana.com

## **About G Medical Innovations**

G Medical (ASX:GMV) was founded in August 2014, aiming to be at the forefront of the digital health revolution, developing the next generation of mobile health (mHealth) technologies. The Company brings forth the experience and expertise of its Board to deliver best-in-class solutions to address this global opportunity.

The Company specialises in innovative next generation mobile and e-health solutions and services using its suite of devices and software solutions with a view to driving multiple and recurring revenue streams, across numerous verticals and territories.

For more information on G Medical, please visit www.gmedinnovations.com