



G Medical Innovations Holdings Ltd  
ARBN 617 204 743

**ASX Announcement**

5 May 2020

## **TGA APPROVAL GRANTED FOR G MEDICAL PATCH**

- **Patch allows for continuous monitoring of patients pre-hospitalisation as well as outpatient cardiac monitoring**
- **Patch allows for up to 6 channel ECG monitoring**
- **All data is compiled with extensive reports sent to hospitals and healthcare professionals**
- **Patch can be programmed to send data on request**
- **TGA certification allows for launch and commercialisation in Australia**

Medical device and telehealth company **G Medical Innovations Holdings Ltd (ASX: GMV)** (“G Medical” or “Company”) is pleased to advise it has been granted Therapeutics Goods Administration (**TGA**) approval for its G Medical Extended Holter Patch (**GMP**).

This marks a significant milestone for the Company as the GMP now officially complies with all relevant Australian medical and safety requirements as a Class IIa medical device.

TGA certification adds to the previously granted European ‘CE’ Class II approval received for the GMP (refer to the Company’s ASX announcement dated 30 November 2017 for further details). The Company is also pursuing required regulatory approvals for its GMP in other target markets, including the USA, and will update shareholders as the regulatory approval processes progress.

### **About the GMP:**

The G Medical Patch (GMP) is part of the modular Vital Signs Monitoring System (VSMS), easy-to-use clinical-grade solution for monitoring patients throughout the healthcare lifecycle.

Ideal for use in clinics, assisted living residences, hospitals and with healthcare providers, the GMP streamlines and simplifies healthcare and patient monitoring by delivering continuous, 14 day recording of 6 channel ECG.

### **Product benefits:**

The GMP seeks to streamline patient monitoring across all stages of the healthcare lifecycle, including pre-hospitalisation, hospitalisation and post-discharge. The product allows for a higher level of patient care, takes the burden off medical personnel, increased efficiency, decreased liability and a reduced number of re-admissions.



The GMP:

- reduces pressure on healthcare providers and personnel while enhancing patient care;
- maximises resources and reduces costs; and
- enables patients to be mobile and move around freely without compromising medical care.

#### **GMP as an Extended Holter**

- 6 channel ECG monitoring system;
- allows for continuous cardiac monitoring of patients, outpatients after hospital discharge for up to 14 days;
- can be programmed to send data on request
- all data is compiled and an extended clinical report is sent to a hospital or physicians;
- single device with comfortable format enhances patient compliance – no wires or extra equipment;
- enhanced patient compliance results in more data that increases diagnostic yields;
- IP (or "Ingress Protection") rating allows daily showering; and
- manual "event" button allows patient to mark a suspected cardiac event.

The GMP assists in diagnosing patients' complaints and conditions remotely via call centres (IDTF).

#### **Management commentary:**

**CEO Dr. Yacov Geva, said:** "TGA certification is a significant milestone for G Medical and demonstrates how the Company's suite of medical devices and telehealth technologies are relevant to the current environment."

"The Company continues to pursue regulatory approvals for both the GMP and the Prizma device in its target markets and looks forward to updating shareholders as they are granted."

**Director and VP Corporate Development Dr. Brendan de Kauwe said:** "The introduction of Telehealth Medicare items numbers has encouraged us to actively pursue entry to into the Australian market."

"Our medical devices and telehealth platforms are becoming recognised as cost effective and scalable solutions to ease the burden on healthcare systems, which can be adopted and utilised by both the patient and their physicians with relative ease."

"Our products are not only effective and relevant in the current COVID-19 pandemic but are also important for the monitoring and remote patient management of patients with chronic diseases as well as other specific medical indications, in parallel and beyond COVID-19".

**Ends**

*Authorised for release by Yacov Geva, Managing Director.*

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**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 leverages 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 using its suite of proprietary devices and software solutions, as well as patient service operations, 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](http://www.gmedinnovations.com)

**About G Medical products:**

G Medical offers a suite of consumer and professional clinical-grade products (with regulatory approval) that are positioned to streamline healthcare services, improve remote access to medical data, reduce costs, improve quality of care, and make healthcare more personalized and precise. Currently the Company is focusing on two main verticals.

The 'Prizma' Medical Smartphone Case is one of two key products developed by G Medical and is aimed at everyday consumers focused on their medical health and wellbeing. The 'Prizma' allows consumers to turn their smartphone into a mobile medical monitor to measure a wide range of vital signs, with the added advantage that users are able to store their medical data in the cloud and share it with third parties such as healthcare professionals and family members.

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