

A WARNING MESSAGE TO ALL AUSTRALIANS

22 March 2023

LifeVac Australia is an Australian-owned company and is the only authorised importer and distributor of the genuine LifeVac™ Airway Clearance Device in Australia, a device that has already saved over 1920 lives after first aid has failed; all without any harm or failure. The genuine LifeVac™ is listed on the Australian Register of Therapeutic Goods (ARTG #285082) as a medical device, as required under law, and has been subject to 2-year long post-market and clinical review and only is sold by LifeVac Australia www.lifevac.net.au and its authorised agents listed on our website.

Since October 2022, LifeVac Australia has been reporting to the regulators, the ACCC, and the Therapeutic Goods Administration (TGA), the growing number of counterfeit (LifeVac copycat) devices being sold in Australia. LifeVac has tested these counterfeit devices, and all have proven to be defective and could result in death or serious and permanent brain injury if relied upon in a choking emergency. Despite the danger posed to thousands of Australians by these fake, defective, illegal copies of the LifeVac device (already sold on various shopping platforms to unsuspecting Australians), the response from these “regulators” has been deafening silence. The ACCC claims that they are “too busy” chasing fake handbags to be concerned with the lives of thousands of Australians and the TGA has done nothing to uphold the Therapeutic Goods Act, which makes it illegal to advertise and/or sell medical devices in Australia without an ARTG registration number or that are dangerous to the public. Penalties for breaches of the Act include; civil and criminal prosecution and substantial fines for businesses.

The TGA has not only allowed e-commerce platforms practical immunity to continue to advertise and sell illegal, counterfeit, and dangerous medical devices to Australians for more than 18 months; but has not issued a single warning, directive, or notice to any person or business engaged in this illegal activity as required under the law, nor warned the public as is the case in the UK. Further, when questioned by the Health Minister (Mark Butler MP) as to their inaction (in not protecting the safety of Australians), officers of the TGA deliberately mislead the Minister as to the facts to avoid responsibility for their failures. The result of this inaction by the regulators has also resulted in an Australian business (abiding by the law) suffering significant financial losses through no fault of its own, in favour of illegal businesses defrauding Australians; therefore, diminishing LifeVac’s ability to save lives.

Australians need to be aware, that our regulator of medical devices, the Therapeutic Goods Administration (TGA), is completely ineffective and uninterested in protecting Australians from dangerous, counterfeit medical devices (including but not limited to the LifeVac™) despite this being part of their primary role under the THERAPEUTIC GOODS ACT 1989, Chapter 5. Part 5.1 and 5.2. Australians should have no faith that Australian regulators like the ACCC or the TGA are acting to protect their safety and that there is any compliance enforcement being carried out concerning counterfeit medical devices. Australians should therefore exercise extreme caution when shopping for medical devices as there is currently no effective regulation, safety evaluation, or any enforcement activity in Australia of counterfeit medical devices by the regulators.

Written and Authorised by S Gould—Owner/Director LifeVac Australia

www.lifevac.net.au