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Australian Government
Department of Health
Therapeutic Goods Administration

Re : Definition and Scope of Medical Device Regulatory Framework

The Australasian Sleep Association (ASA) is the peak scientific body in Australia & New Zealand representing clinicians, scientists and researchers in the broad area of Sleep. Our vision is the provision of world standard research, education and training, and establishment of clinical standards to ensure clinical best practice in sleep medicine resulting in an informed community with healthy sleep practices.

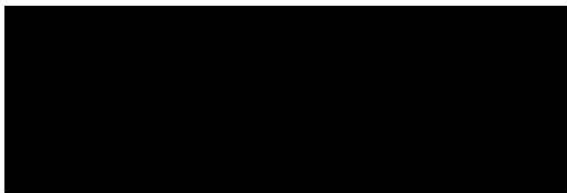
ASA endorses the proposal to align the Australian definitions of devices to the EU definitions. We believe that the EU definitions are much clearer and easier to understand than the Australian definitions.

This will relate directly to the diagnosis and treatments for Obstructive Sleep Apnoea with CPAP machines, and the necessary masks and tubing that are necessary for the treatment. When handling patients fro

We believe that this will assist in raising issues in regard to the machines and manufacturers to both the companies and the TGA.

Should you require any further information in this regard please do not hesitate to contact me at peter.eastwood@health.wa.gov.au.

Kind regards



Peter Eastwood
President