Australia New Zealand Industrial Gas Association

18 February 2019

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

devicereforms@tga.gov.au

Dear Sir/Madam,

Re: **Consultation: Potential reclassification of active medical devices for diagnosis and patient therapy**

The Australia New Zealand Industrial Gas Association (ANZIGA) is the peak industry association representing companies that produce and distribute industrial gases, including bulk and compressed gas for the industrial, medical, food, scientific and hospitality markets (referred as Industrial Gases) in Australia and New Zealand.

ANZIGA welcomes the opportunity to provide comments on the TGA Consultation - *Potential reclassification of active medical devices for diagnosis and patient therapy*.

The consultation paper invites feedback on other medical devices that may be covered by the EU MD Regulation 22 and continuous positive airway pressure (CPAP) devices are included in this list. ANZIGA believes that the CPAP devices should not be captured by this alignment to EU regulation.

The EU Rule 22 states:

> Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.

ANZIGA believes that CPAP devices with an auto-pressure adjustment function, which only deliver tiny amounts of air pressure (up to 20cmH2O) is insignificant, when compared to automated external defibrillators (AED)which potentially shock the patient with 2000V/20Amps of electricity.

ANZIGA requests that TGA should establish appropriate guidance to explain what level of impact by a device to patient management is deemed “Significant”. This will ensure that any reclassification under EU Rule 22 does not unintentionally risk catching low to medium risk devices.

Please do not hesitate to contact ANZIGA if further information to support this submission is required.

Kind Regards,

[redacted]

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