

## Regulatory approvals expand CleanSpace's market opportunities

- CleanSpace HALO meets New Zealand's Medsafe requirements and is added to WAND database
- AX chemical filter receives international approval for ANZ and European markets

CleanSpace Holdings' (ASX: CSX; CleanSpace) industry leading healthcare respirator, CleanSpace HALO, has been added to New Zealand's Web Assisted Notification of Devices (WAND) database after meeting the NZ Medical Devices Safety Authority (Medsafe) regulatory requirements. In addition, CleanSpace has received international approvals for a combined AX chemical filter that expands its industrial product range.

The WAND registration and AX filter approvals demonstrate how CleanSpace is investing in product development and regulatory compliance to expand its market opportunities and drive sales growth.

### Medsafe registration opens the NZ healthcare market

The WAND listing enables CleanSpace HALO to be purchased and used by New Zealand healthcare providers. New Zealand's healthcare system is comprised of 220 public and private hospitals. Approximately 85% of New Zealand's healthcare is government-funded and delivered through a network of 20 District Health Boards (DHBs). CleanSpace has begun hospital trials in New Zealand.

The importance of internationally recognised certifications and approvals has been highlighted recently following increased reporting of counterfeit and poor quality filtering facepiece respirators (FFRs) and personal protective equipment (PPE). US regulators recently banned the products of one of the world's largest manufacturers of N95 masks due to unsatisfactory quality management systems.

CleanSpace HALO holds the highest levels of approvals internationally, including Australia's Therapeutic Goods Administration (TGA), USA's National Institute for Occupational Safety and Health (NIOSH) and Europe's CE mark. The Company's Steri-Plus filter was designed last year to meet the urgent needs of hospital infection control teams and has also attained the necessary international approvals.

CleanSpace HALO is the only powered air purifying respirator (PAPR) specifically designed and built for use in clinical settings, in consultation with healthcare professionals.

### AX filter approvals expand CleanSpace reach into chemical markets in Europe, Australia and New Zealand

CleanSpace continues to innovate for large chemical sectors with the release of an AX filter to be used with its industrial PAPR range. The Company has developed and successfully received approval of a combined AX P2 TM2 filter for Europe (EN12942) and Australia/NZ (AS1715). The AX filter complements CleanSpace's wide range of filters including particulate and combination particulate/gas filters.

The AX TM2 P2 filter expands the usability of CleanSpace PAPRs in organic chemical handling within industrial settings such as chemical processing, pharmaceutical production, aerospace, industrial fumigation, and energy, oil & gas. The AX TM2 P2 filter is suitable for personal worker protection

against organic compounds with a low boiling point ( $\leq 65^{\circ}\text{C}$ ) (e.g. methyl bromide, methanol, acetone) as well as against airborne particulates (e.g. dust, mists and fumes). The filtration efficiency for particulates is  $> 99.5\%$  for  $0.3\mu\text{m}$  particles or above. CleanSpace is the only PAPR available for use with an AX TM2 P2 filter.

“Respiratory protection has never been more important. Employers should be able to purchase reliable equipment and workers should be able to wear their PPE with confidence. The Delta variant serves as a reminder that highly protective, approved mask solutions are essential for at risk workers. CleanSpace PAPRs are fully approved and widely used in clinical settings for the protection against airborne hazards and are the best practice for high-risk settings,” CleanSpace CEO Dr Alex Birrell said.

**Authorised for release by the CleanSpace Holdings Limited Board of Directors**

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#### **FOR MORE INFORMATION**

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#### **ABOUT CLEANSPACE TECHNOLOGY**

CleanSpace is a Sydney-based designer and manufacturer of respiratory protection equipment for healthcare and industrial applications, founded by a team of biomedical engineers with experience in respiratory medicine devices. CleanSpace is passionate about continually improving health outcomes, workplace safety and standards of care. In the last 20 years, technology has driven unprecedented advances in medical equipment and transformed people’s health. We have brought this to personal respiratory protection. The Company continues to invest in research and development programs resulting in differentiated design and approved products that provide compelling employer and user benefits, namely, higher protection with improved compliance and productivity. CleanSpace Respirators are a true game changer, changing the way people on the front lines think about respiratory protection.

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