

EUROPEAN CE MARK CERTIFICATION FOR MICRO-X ROVER

Micro-X's branded Rover and Rover Plus mobile x-ray system receives CE marking under new EU MDR Regulations

Adelaide, Australia, 26th October 2023: Micro-X Ltd (ASX:MX1) (**Micro-X** or the **Company**), a leader in cold cathode x-ray technology for health and security markets globally, is pleased to announce that Micro-X has received CE Mark Certification under the European Medical Device Regulation (MDR) for its Class IIb medical device, the Rover and Rover Plus mobile x-ray system (**Rover**), allowing it to be sold for medical use in the European Union (EU) and other countries that recognise the certification.

Key Points

- **Micro-X branded Rover mobile x-ray system - now available for commercial sale in the European Union**
- **Micro-X has an existing network of EMEA distributors and pipeline of potential customers**
- **EU is second largest imaging market globally - comprising 32 countries and nearly 500 million people - providing an addressable mobile x-ray market of approximately A\$80m annually**

To receive CE marking, medical device companies must comply with the European Commission Regulation (EU) No. 2017/745, commonly known as the Medical Device Regulation (MDR).

The CE marking indicates that a product has been assessed and deemed to meet EU safety, health and environment protection requirements. Compliance with this regulation is mandatory for medical device companies to legally market and sell their products in the EEA (European Economic Area). Recent MDR mandates have raised the bar for manufacturers, requiring them to meet more stringent guidelines and detailed analysis of clinical data about a medical device to support safety and performance.

Receiving CE marking for the Rover is a significant achievement for Micro-X and enables opportunities for geographic expansion to 32 countries in the EEA as well as other countries where CE mark is recognised including the UK and Switzerland.

The EEA has a population of nearly 500 million and forms one of the largest healthcare markets globally. The current addressable EU market for mobile x-ray systems is approximately A\$80 million and continues to grow.

Micro-X already has several distributors and dealerships in the EMEA region and expects to sign additional dealers in the short term as these have been awaiting approval for sale.

The Micro-X Rover is now able to be marketed in key global markets, subject to local registrations, that recognise FDA 510(k) clearance, CE marking and listing on the Australian Register of Therapeutic Goods.

Micro-X's Chief Executive Officer, Kingsley Hall, commented:

"Receiving this CE marking opens a huge market opportunity for our Mobile DR range in Europe, where we have distributors and direct sales staff already in place. The team are now ramping up discussions with potential customers that were awaiting this certification with a view to securing near term sales. With our proprietary Micro-X Rover now able to be sold commercially in all key global markets, we look forward to executing our strategy to grow commercial sales and bring our technology to the world."

This ASX Announcement is authorised by the Board of Micro-X.

– ENDS –

About Micro-X

Micro-X Limited (the **Company**) is an ASX listed hi-tech company developing and commercialising a range of innovative products for global health and security markets, based on proprietary cold cathode, carbon nanotube (CNT) emitter technology. The electronic control of emitters with this technology enables x-ray products with significant reduction in size, weight and power requirements, enabling greater mobility and ease of use in existing x-ray markets and a range of new and unique security and defence applications. Micro-X has a fully vertically integrated design and production facility in Adelaide, Australia. A growing technical and commercial team based in Seattle is rapidly expanding Micro-X's US business.

Micro-X's product portfolio is built in four, high margin, product lines in health and security. The first commercial mobile digital radiology products are currently sold for diagnostic imaging in global healthcare, military and veterinary applications. An X-ray Camera for security imaging of Improvised Explosive Devices is in advanced development. The US Department of Homeland Security has selected Micro-X to design a next-generation Airport Checkpoint Portal with self-service x-ray. A miniature brain CT imager for pre-hospital stroke diagnosis in ambulances, is being developed with funding from the Australian Government's Medical Research Future Fund.

For more information visit: www.micro-x.com

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