

FINAL ROVER COMPLIANCE TESTS COMPLETED

Testing results to support planned FDA 510(k) submission within coming weeks

Adelaide, Australia, 1st June 2020: Australian hi-tech company Micro-X Ltd (ASX:MX1) (**Micro-X** or the **Company**), a leader in cold cathode x-ray technology for health and security markets globally, provides the following Market Update on the commercialisation progress of its second product, the Rover mobile X-ray for deployed military hospitals (**Rover**).

Key Points

- **Rover compliance testing completed**
- **Final requirement for Rover FDA 510(k) submission**
- **FDA submission planned in coming weeks**

Rover commercialisation

Micro-X has successfully completed the electrical and mechanical safety test program on the Rover with the receipt of formal notification of the results of Electro-Magnetic Compatibility testing, conducted at a specialist laboratory in Melbourne. The series of IEC 60601-1 tests in the program was supervised by our independent Notified Body which has now issued a formal test report to document that the Rover meets the international safety requirements for a Class II medical device.

This IEC 60601-1 test report for the Rover is the final element required for the Rover 510(k) submission to the United States Food and Drug Administration (**FDA**). The dossier for submission to the FDA is being completed with Micro-X's regulatory advisers for lodgement in coming weeks.

Subject to FDA granting approval, this first generation Rover will then be available for sale in the United States including to the US Army Medical Materiel Agency who have expressed strong interest in trialling the Rover. Regulatory filings in other jurisdictions including Europe and Australia are also planned to enable sales to UK Ministry of Defence and the Australian Defence Force.

Additionally, the high power generator for the Rover has now moved into the execution phase with the funds from the recent \$15 million Placement and Entitlement Offer. This project which is expected to take 9 – 12 months is another key step in the commercialisation of the Rover Mark II, the high power version of the Rover intended for volume sales following regulatory approval.

Micro-X's Managing Director, Peter Rowland, commented:

"We are excited that this successful testing marks the conclusion of the design phase of the first product which Micro-X will take to market under its own name and brand. The Rover will also be the first mobile X-ray unit which has been purpose-designed for deployed military operations and which incorporates many features specifically requested by military users to optimise its performance in this demanding deployed environment. We are focussing our sales efforts in being able to secure a first sale of the Rover this year and to facilitate that we plan to lodge a 510(k) submission with the FDA in the coming weeks."

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

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About Micro-X

Micro-X Limited (the **Company**) is an ASX listed hi-tech company developing and commercialising a range of innovative products for the global health and security markets, based on proprietary cold cathode, carbon nanotube emitter technology. The electronic control of emitters with this

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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. The Company has its core R&D, engineering and production capability at its facility in Adelaide, Australia.

The Company's first product, the *Carestream DRX Revolution Nano*, is an ultra-lightweight digital medical x-ray system for the rapidly expanding mobile x-ray market in hospitals and healthcare. The *Carestream DRX Revolution Nano* holds 510(k) and CE Mark certifications and is sold commercially in a number of global markets by the Company's exclusive distributor, Carestream Health, Inc. The Company has a portfolio of innovative products in development, aimed at customer solutions where there is little or no competition. This includes the Mobile Backscatter Imager or MBI which will image Improvised Explosive Devices for airport security, defence and counter-terrorism applications. The MBI is being jointly developed in partnership with Thales, a global supplier of defence and security technology systems, who are providing technical support and \$10 million of funding.

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