

The Manager
Company Announcements Office
ASX Limited

CE MARK SELF CERTIFICATION FINALISED FOR APAS®

Adelaide, Australia, 23 June 2017: Australian medical technology company LBT Innovations Limited (ASX: LBT) and joint venture company Clever Culture Systems AG (CCS) have completed a comprehensive essential requirements review of the extensive documentation and data packs related to the APAS® technology and certify requirements are met for CE Marking.

LBT CEO and Managing Director Brent Barnes said, "This process required our internal engineering and quality teams to work closely with our regulatory consultants to complete a thorough checklist to ensure all requirements were met. We are satisfied that given the exhaustive and rigorous testing and data including a 10,000 patient international clinical trial which supported the FDA clearance, we meet the requirements for CE Mark certification. It's an important milestone to achieve as we look to firm up distribution partner(s) in the European region, and gives potential distributors confidence in our ability to deliver a product in their markets".

Completing this process means that we have de-risked our regulatory path to market in all key global markets: North America, Europe and Australia and New Zealand.

APAS® is an unclassified, self-declarable in vitro diagnostic (IVD) medical device in Europe and can subsequently be CE marked by the manufacturer once a signed Declaration of Conformity is completed which states all of the necessary safety and performance evidence (data) is met, to support compliance with European regulatory requirements.

Some countries within Europe, such as United Kingdom, Germany and others, require a country specific registration of the APAS® Independence instrument, which is a simple paperwork process that will occur closer to when the instrument is available in the market. The important milestone of having CE Marking is a pre-cursor to this, which has now been achieved.

APAS® is a breakthrough artificial intelligence technology for the automated imaging, image analysis, interpretation and reporting of growth on microbiology culture plates after incubation. The APAS® independence improves the clinical efficiency of microbiology labs and enables faster diagnosis and reporting of infectious diseases. The US FDA-cleared device is based on LBT's Australian-developed intelligent imaging and interpretative software and based in a unit about the size of a large photo-copier.

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About LBT Innovations

LBT Innovations (LBT) improves patient outcomes by making healthcare more efficient. Based in Adelaide, South Australia, the Company has two world class-leading products in microbiology automation: MicroStreak®, which provides automated culture plate streaking and Automated Plate Assessment System (APAS®). Based on LBT's intelligent imaging and interpretative software, US FDA-cleared APAS® automates imaging, analysis and interpretation of culture plates following incubation. LBT has entered into a joint venture Clever Culture Systems AG (CCS) with Hettich Holding Beteiligungs- und Verwaltungs-GmbH to commercialise APAS® products. LBT's third product WoundVue® is in early development; this is a proposed automated solution to assist in the management of chronic wounds.

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