

NZX/ASX Announcement

19 December 2025

TruScreen investigates commercial opportunities for Western Europe and the Middle East

- **TruScreen's India distributor, Renovate Biologicals Pvt Ltd has been authorised to investigate commercial opportunities in Western Europe and the Middle East**
- **TruScreen to be launched for Europe and the Middle East at the upcoming World Health Expo in Dubai in February 2026**
- **Middle East countries have an estimated screening population of 99.7 million women***
- **Western European countries have an estimated screening population of 84.3 million women***

TruScreen Group Limited ("TruScreen" or "the Company") advises that it has authorised Renovate Biologicals Pvt Ltd (Renovate) to investigate commercial and market opportunities in the Middle East and Western Europe from 1 January 2026.

Middle Eastern commercial activity has been authorised for Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, UAE, Lebanon, Iraq, Yemen, Iran and Turkey. These countries have an estimated screening population of 99.7 million women*. Renovate will represent TruScreen at the [World Health Expo](#) in Dubai from Feb 9 - 12, 2026.

Western European commercial activity has been authorised for Finland, United Kingdom, Netherlands, Belgium, Denmark, France, Sweden and Germany. These countries have an estimated screening population of 84.3 million women*.

The TruScreen medical device is CE Mark (Conformité Européenne), certifying that it meets essential EU health, safety, and environmental standards and allowing it to be sold freely within the European Union.

Renovate is a fast-growing international medical device distributor who was appointed, in April 2025, to distribute the TruScreen medical device in India. Established in 2015 in Hyderabad, Renovate distributes gold standard, advanced and innovative technologies which have transformed clinical outcomes in Diagnostics, Therapeutics, Critical Care, Organ Transplantation, Hematology and Ophthalmology to global markets.

Renovate's leadership team has a combined experience of over 50-man years and are supported by a rapidly expanding sales team and network of sub-distributors, with offices in Hyderabad, Singapore, Dubai and Amsterdam. The team aims to gain a 70-80% share of the cervical cancer screening device market by 2030.

TruScreen CEO, Martin Dillon commented:

"It is incredibly exciting to be launching TruScreen's next phase of global marketing activity with Renovate. They are well positioned to support our continued global expansion, connecting us with government and screening initiative leaders."

Western Europe has had a focus on cervical cancer for many years, and Middle Eastern countries have been increasing their efforts on women's health. Significant barriers to full population screening remain and many of these countries are long way off meeting WHO target rates (70% by 2030), so the opportunity for TruScreen to have an impact on the incidence and mortality from cervical cancer in these regions is real."

This announcement has been approved by the Board.

* CIA World Factbook (female population aged 15-64yrs)

Ends

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About TruScreen:

TruScreen Group Limited (NZX/ASX: TRU) is a medical device company that has developed and manufactures an AI-enabled device for detecting abnormalities in the cervical tissue in real-time via measurements of the low level of optical and electrical stimuli.

TruScreen's cervical screening technology enables cervical screening, negating sampling and processing of biological tissues, failed samples, missed follow-up, discomfort, and the need for costly, specialised personnel and supporting laboratory infrastructure.

The TruScreen device, TruScreen Ultra®, is registered as a primary screening device for cervical cancer screening.

The device is CE Marked/EC certified, ISO 13485 compliant and is registered for clinical use with the TGA (Australia), MHRA (UK), NMPA (China), SFDA (Saudi Arabia), Roszdravnadzor (Russia), and COFEPRIS (Mexico). It has Ministry of Health approval for use in Vietnam, Israel, Ukraine, and the Philippines, among others and has distributors in 29 countries. In 2021, TruScreen established a manufacturing facility in China for devices marketed and sold in China.

TruScreen technology has been recognised in CSCCP's (Chinese Society for Colposcopy and Cervical Pathology) China Cervical Cancer Screening Management Guideline.

TruScreen has been recognised in a China Blue Paper "Cervical Cancer Three Stage Standardized Prevent and Treatment" published on 28 April 2023.

In Dec 2023 TruScreen technology was added to the Vietnam Ministry of Health approved National Technical List, for use in Vietnam's public and private healthcare sectors and in 2024 was added to the Russian guidelines for the screening of cervical cancer.

In financial year 2024 alone, over 200,000* examinations were performed with the TruScreen device. To date, over 200 devices have been installed and used in China, Vietnam, Mexico, Zimbabwe, Russia, and Saudi Arabia. TruScreen's vision is "A world without the cervical cancer"®.

To learn more, please visit: www.truscreen.com/.

**Based on Single Use Sensor sales.*

Glossary:

Pap smear (the Papanicolaou smear) test involves gathering a sample of cells from the cervix, with a special brush. The sample is placed on a glass slide or in a bottle containing a solution to preserve the cells. Then it is sent to a laboratory for a pathologist to examine under a microscope. <https://www.cancer.net/navigating-cancer-care/diagnosing-cancer/tests-andprocedures/pap-test>

LBC (the liquid-based cytology) test, transfers a thin layer of cells, collected with a brush from the cervix, onto a slide after removing blood or mucus from the sample. The sample is preserved so other tests can be done at the same time, such as the human papillomavirus (HPV) test <https://www.cancer.net/cancer-types/cervical-cancer/diagnosis>

HPV (human papilloma virus) test is done on a sample of cells removed from the cervix, the same sample used for the Pap test or LBC. This sample is tested for the strains of HPV most commonly linked to cervical cancer. HPV testing may be done by itself or combined with a Pap test and/or LBC. This test may also be done on a sample of cells which a person can collect on their own. <https://www.cancer.net/cancer-types/cervical-cancer/screening-and-prevention>

Sensitivity and specificity mathematically describe the accuracy of a test which reports the presence or absence of a condition. If individuals who have the condition are considered "positive" and those who don't are considered "negative", then sensitivity is a measure of how well a test can identify true positives and specificity is a measure of how well a test can identify true negatives:

- **Sensitivity** (true positive rate) is the probability of a positive test result, [conditioned](#) on the individual truly being positive.
- **Specificity** (true negative rate) is the probability of a negative test result, conditioned on the individual truly being negative ([Sensitivity and specificity – Wikipedia](#)).

For more information about the cervical cancer and cervical cancer screening in New Zealand and Australia, please see useful links:

New Zealand: [National Cervical Screening Programme](#) | [National Screening Unit \(nsu.govt.nz\)](#)

Australia: [Cervical cancer](#) | [Causes, Symptoms & Treatments](#) | [Cancer Council](#)