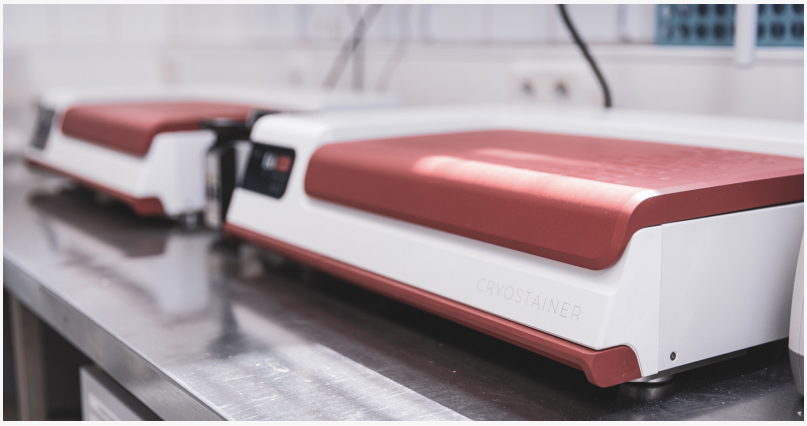
X-ZELL Next-Generation Cytology (NGC) platform now IVDR-compliant and FDA-listed

Medical technology company achieves direct market access



X-ZELL Cryoimmunostaining™ Suite

SINGAPORE, March 21, 2024 /EINPresswire.com/ -- X-ZELL is proud to announce that the company's ground-breaking Next-Generation Cytology (NGC) technology is now officially available for routine use in Europe and the US.

X-ZELL NGC is a platform technology combining next-generation immunostaining with digital imaging to facilitate same-day cancer diagnoses from minimally invasive samples in routine laboratories worldwide.

> After years of development and testing, we are incredibly proud that our NGC platform and accessories are now IVDR- and MDR-compliant, CE-marked and FDA-listed."
> *Dr Sebastian Bhakdi, Founder & CEO*

After undergoing extensive testing in Singapore and Germany, the platform's two core systems, the X-ZELL Cryoimmunostaining™ Suite and the X-ZELL Hybrid Microscope, have now been listed with the United States Food and Drug Administration (FDA).

In compliance with EU Regulations 2017/746 (In-Vitro Diagnostics Regulation, IVDR) and 2017/745 (Medical Device Regulation, MDR), they have also been listed on the European Union's EUDAMED database.

Milestone achieved

"After years of development and testing, we are incredibly proud that our NGC platform and accessories are now IVDR- and MDR-compliant, CE-marked and FDA-listed," commented X-ZELL Founder & CEO, Dr Sebastian Bhakdi. "Achieving this milestone will finally make the technology available for a wider routine audience – potentially impacting millions of lives worldwide."

Insufficient standard

While minimally invasive cancer surgery has been on the rise for decades, minimally invasive diagnostic testing still plays a secondary role in modern cancer care, with an estimated 70-80% of diagnostic samples still derived from surgical tissue, requiring invasive collection procedures.

Current processing techniques such as cell-blocking and immunohistochemistry (IHC) have not been optimised for minimally invasive sample types, forcing some laboratories to use them 'off-label' as a self-validated workaround. The results are slow turnaround times of 48 hours or more and a high risk of non-diagnoses due to low cellular yield or technical issues such as background or non-specific staining [1, 2].


X-ZELL Hybrid Microscope


X-ZELL Founder & CEO, Dr Sebastian Bhakdi

Powerful laboratory tool

X-ZELL NGC is a powerful new laboratory tool that was specifically designed for handling minimally invasive samples such as body liquids or fine-needle aspirations (FNA). Real-life testing in user laboratories has shown that it can reduce the time from sample to diagnosis from an average of 48 to under four hours by omitting 95% of the preparation work required under IHC [3].

Using X-ZELL's patented eight-channel multiplexing technology, short Cryoimmunostaining™, it can extract up to 700 per cent more diagnostic data per sample and save up to 40% of manual handling along the way. The results are displayed side-by-side in a digital format – a first in minimally invasive cytological testing [3].

"NGC will help pathologists make more informed diagnostic decisions from minimally invasive samples, in a fraction of the time," said Dr Bhakdi. "It's exciting to see that the system is now FDA- and EUDAMED-listed in compliance with IVDR and MDR and finally ready to make the leap from research to routine."

[1] Like most immunostaining methods, X-ZELL NGC is typically used in conjunction with conventional histological staining, such as hematoxylin eosin (H&E) staining, as a first-line assessment.
[2] Kirbiš et al. 2020, doi 10.1002/cncy.22311
[3] X-ZELL data, derived from comparative testing at MVZ Frankfurt, Germany.

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