

30 July 2024

## Re: ZytoVision IVDR Update Notification

Dear ZytoVision user,

Abacus dx are thrilled to announce ZytoVision received their In Vitro Diagnostics Regulation (IVDR) certification for its selected product portfolio. The approval of IVDR allows customers to have continued access to products of the highest quality that meet the latest and strictest EU requirements.

This milestone marks a significant step forward to ZytoVision's commitment to excellence and their dedication to push the boundaries for medical devices offered to healthcare professionals and their patients worldwide. The IVDR sets rigorous requirements for the quality, safety and performance of in vitro diagnostic devices. Due to the high quality standards of the products used in medical diagnostics, patient safety is increased.

Starting from June 2024, ZytoVision have begun transitioning the IVDR certified probes. This change of labels (from IVDD to IVDR) will occur over time whenever a new batch is produced, so the changeover to IVDR takes place at a different time for each product. Each new batch of a certified product is provided with IVDR-compliant manufacturer information. We will only notify you when a specific probe is being transitioned if it may affect your ordering schedule, so you don't experience any product delays. Users may continue to use the IVDD products until the expiration date is reached.

The assay procedures described in the instruction manuals did not change. Customers can continue to work with ZytoVision products in exactly the same way as before. You may notice some intended purposes have become more specific. You must ensure the probe is validated for the correct intended purpose. If the probes were used for the analyses of cancer types that are not covered by the intended purpose, but you have previously validated these cancer types, then re-validation is not required, as the probe design has not changed.

You can keep up to date with the latest changes to the product status by contacting your Abacus dx representative, visiting the ZytoVision website, viewing the latest instructions for use and checking the labels of the products.

Please don't hesitate to reach out if you have any questions.

Kind Regards,

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