

**ZYTOMICS****ZYTOVISION**
Molecular diagnostics simplified

IVDR-certified Portfolio

The certification under the new In Vitro Diagnostics Regulation (EU) 2017/746 (IVDR) is mandatory for manufacturers of in vitro diagnostic devices (IVDs). The IVDR replaces the In Vitro Diagnostics Directive (EU) 98/79/EC (IVDD).

ZytoVision received the IVDR certification in May 2024 and has already started the transition of its portfolio. In line with our commitment to conformity and compliance, we have listed below the Class C products that are already IVDR-labeled and meet the latest and strictest EU requirements:

Product Name	Product No.
ZytoDot SPEC ERBB2 Probe	C-3001-400
ZytoDot SPEC ERBB2 Probe Kit	C-3003-40
ZytoDot SPEC MDM2 Probe	C-3012-400
ZytoDot 2C SPEC ERBB2/CEN 17 Probe Kit	C-3022-10/-40
ZytoDot 2C SPEC ERBB2/CEN 17 Probe	C-3032-100/-400
ZytoDot 2C SPEC 1p36/1q25 Probe	C-3036-100/-400
ZytoDot 2C SPEC 19q13/19p13 Probe	C-3037-100/-400
ZytoDot 2C SPEC MDM2/CEN 12 Probe	C-3049-100/-400
ZytoDot 2C SPEC ALK Break Apart Probe	C-3055-100/-400
ZytoDot 2C SPEC MET/CEN 7 Probe	C-3057-400
ZytoDot 2C SPEC ROS1 Break Apart Probe	C-3063-100/-400
ZytoDot 2C SPEC MYC Break Apart Probe	C-3066-400
ZytoDot 2C SPEC IGH Break Apart Probe	C-3071-100
ZytoDot 2C SPEC BCL2 Break Apart Probe	C-3073-100
ZytoDot 2C SPEC BCL6 Break Apart Probe	C-3074-100
ZytoFast HPV type 6/11 Probe	T-1055-400
ZytoFast HPV type 16/18 Probe	T-1056-400
ZytoFast HPV type 31/33 Probe	T-1057-400
ZytoFast EBV Probe	T-1114-400
ZytoFast human Ig-kappa Probe	T-1115-400
ZytoFast HPV High-Risk (HR) Types Probe	T-1140-400
ZytoLight CEN 8 Probe	Z-2004-50/-200
ZytoLight SPEC MDM2/CEN 12 Dual Color Probe	Z-2013-50/-200
ZytoLight SPEC MAML2 Dual Color Break Apart Probe	Z-2014-50/-200
ZytoLight SPEC ERBB2/CEN 17 Dual Color Probe	Z-2015-50/-200
ZytoLight SPEC ERBB2/CEN 17 Dual Color Probe Kit	Z-2020-5/-20
ZytoLight SPEC CDKN2A/CEN 9 Dual Color Probe	Z-2063-50/-200
ZytoLight SPEC FGFR1/CEN 8 Dual Color Probe	Z-2072-50/-200
ZytoLight SPEC 19q13/19p13 Dual Color Probe	Z-2076-50/-200
ZytoLight CEN 17/SPEC ERBB2 Dual Color Probe	Z-2077-50/-200
ZytoLight SPEC CDKN2A/CEN 3/7/17 Quadruple Color Probe	Z-2081-50/-200

Product Name	Product No.
ZytoLight SPEC MET/CEN 7 Dual Color Probe	Z-2087-50/-200
ZytoLight SPEC MYC Dual Color Break Apart Probe	Z-2090-50/-200
ZytoLight SPEC ERBB2/TOP2A/CEN 17 Triple Color Probe	Z-2093-50/-200
ZytoLight SPEC EWSR1 Dual Color Break Apart Probe	Z-2096-50/-200
ZytoLight SPEC CCND1 Dual Color Break Apart Probe	Z-2108-50/-200
ZytoLight SPEC TFE3 Dual Color Break Apart Probe	Z-2109-50/-200
ZytoLight SPEC IGH Dual Color Break Apart Probe	Z-2110-50/-200
ZytoLight SPEC BCL2/IGH Dual Color Dual Fusion Probe	Z-2114-50/-200
ZytoLight SPEC COL1A1/PDGFB Dual Color Dual Fusion Probe	Z-2116-50/-200
ZytoLight SPEC ALK/EML4 TriCheck™ Probe	Z-2117-50/-200
ZytoLight SPEC PDGFB Dual Color Break Apart Probe	Z-2119-50/-200
ZytoLight SPEC FGFR2/CEN 10 Dual Color Probe	Z-2122-200
ZytoLight SPEC ALK Dual Color Break Apart Probe	Z-2124-50/-200
ZytoLight SPEC FUS Dual Color Break Apart Probe	Z-2130-50
ZytoLight SPEC MYB Dual Color Break Apart Probe	Z-2143-50/-200
ZytoLight SPEC ROS1 Dual Color Break Apart Probe	Z-2144-50/-200
ZytoLight SPEC RET Dual Color Break Apart Probe	Z-2148-50/-200
FlexISH ERBB2/CEN 17 Dual Color Probe	Z-2166-50/-200
ZytoLight SPEC NTRK1 Dual Color Break Apart Probe	Z-2167-50/-200
ZytoLight SPEC FGFR3 Dual Color Break Apart Probe	Z-2170-50/-200
ZytoLight SPEC YWHAE Dual Color Break Apart Probe	Z-2175-50
ZytoLight SPEC BCL6 Dual Color Break Apart Probe	Z-2177-50/-200
ZytoLight SPEC ERBB2/D17S122 Dual Color Probe	Z-2190-50/-200
ZytoLight SPEC BCL2 Dual Color Break Apart Probe	Z-2192-50/-200
ZytoLight SPEC ABL1 Dual Color Break Apart Probe	Z-2199-50
FlexISH ALK/ROS1 DistinguISH™ Probe	Z-2203-50/-200
ZytoLight SPEC NTRK2 Dual Color Break Apart Probe	Z-2205-50/-200
ZytoLight SPEC NTRK3 Dual Color Break Apart Probe	Z-2206-50/-200
ZytoLight SPEC CUX1/EZH2/CEN 7 Triple Color Probe	Z-2210-50
ZytoLight SPEC IRF4,DUSP22 Dual Color Break Apart Probe	Z-2214-50
ZytoMation ERBB2/CEN 17 Dual Color FISH Probe	Z-2292-5.1ML
ZytoMation ROS1 Dual Color Break Apart FISH Probe	Z-2298-5.1ML
ZytoMation BCL2 Dual Color Break Apart FISH Probe	Z-2306-5.1ML
ZytoLight SPEC MALT1/IGH Dual Color Dual Fusion Probe	Z-2325-50
ZytoLight SPEC NECTIN4/1p12 Dual Color Probe	Z-2331-50/-200

We do it
for you

- Continued access to our product portfolio: production and quality standards remain unchanged
- Undisturbed work in diagnostics without having to carry out time-consuming validations
- Accuracy and reliability in diagnostics: increased patient safety due to the high quality standards of the products
- Risk minimization

More about our IVDR journey

Step by step we change the status of our probes! No action required from your side: product names and order numbers remain the same.

Although many probes are already IVDR certified, we currently continue to offer you IVDD probes for most of the IVDR portfolio. This complies with IVDR regulations.

Stay tuned for continuous updates on the development of our IVDR product portfolio. We will continuously notify you about any IVDR probe releases.

Questions?

Feel free to contact us: helptech@zytovision.com

17.07.2025 V22

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