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CytoCell

IVDR-Certified FISH Probes

We're committed to transitioning our IVDD portfolio to IVDR before 31 December 2028

Why choose CytoCell?

High-intensity signals with optimised FISH probes for clear localised and bright signals

Rapid on-site and digital support from technical and clinical specialists who understand the needs of fast-paced, quality-driven labs

Straightforward transition with regular IVDR probe releases and no revalidation for existing users

IVDR Explained

IVDR (Regulation (EU) 2017/746) replaced the previous IVDD (Directive 98/79/EC) framework and introduced more stringent requirements for the quality, safety, performance and traceability of *in vitro* diagnostic (IVD) medical devices.

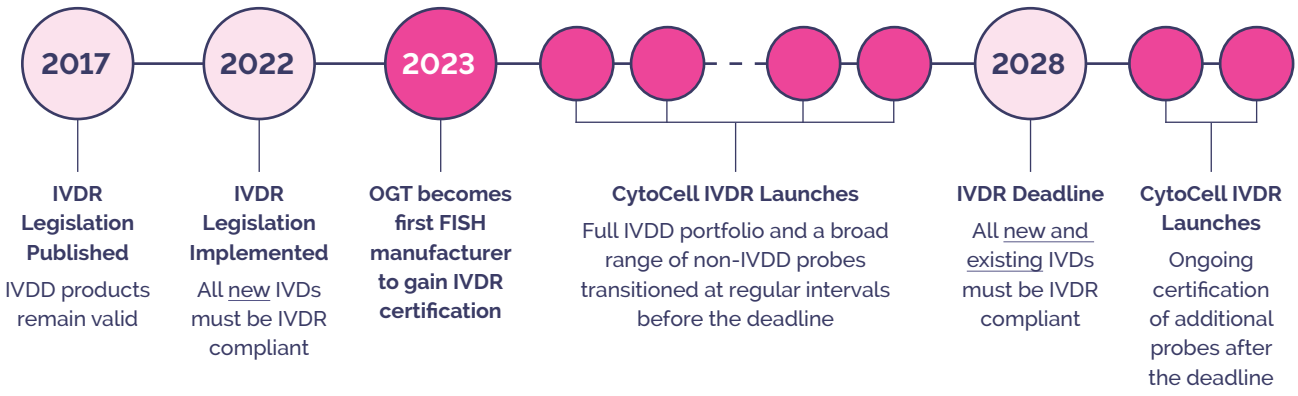
After the 31 December 2028 deadline, FISH must be IVDR compliant or be removed from the IVD market.

For FISH probes, this means greater regulatory scrutiny, including stronger technical documentation, clinical evidence and Notified Body review for higher-risk devices such as Class C assays.

For laboratories, choosing IVDR-certified probes supports continued access to compliant, traceable diagnostics and provides greater confidence in long-term testing continuity.

Our IVDR Commitment

The full CytoCell® IVDD portfolio will be transitioned to IVDR, alongside a broad range of non-IVDD catalogue probes and existing custom myProbes.



"We are committed to providing our customers with products that meet their needs, their patients' needs, and the highest standards of regulatory compliance.

At OGT, we were the first FISH manufacturer to introduce IVDR-certified CytoCell FISH probes and these probes are designed and manufactured with the same level of excellence our customers expect from CytoCell.

The IVDR certification formally recognises their quality, safety and performance, giving laboratories confidence in both their results and their regulatory readiness. Our priority is to ensure customers have robust, reliable products, and a FISH partner they can depend on."

Faidra Partheniou
Vice President, Regulatory and Medical Affairs at OGT

CytoCell IVDR-Certified FISH Probes

CytoCell's expanding IVDR portfolio delivers broad coverage across haematological malignancies and prenatal applications, with a clear roadmap to full IVDR transition ahead of the 31 December 2028 deadline.

This ensures continuity of supply and regulatory confidence, enabling you to move seamlessly from IVDD to IVDR with a trusted partner.

Supported by a comprehensive portfolio and expert guidance throughout validation and implementation, you can switch with confidence.

	Probe Name	Supported disease	Chromosome Region	Cat. No.
Haematological malignancies	AML1 (RUNX1) Breakapart Probe	AML, ALL	21q22.1	CE-LPH 027
	AML1/ETO (RUNX1/RUNX1T1) Translocation, Dual Fusion Probe	AML	8q21.3 21q22.1	CE-LPH 026
	BCR/ABL (ABL1) Translocation, Dual Fusion Probe	CML, AML, ALL	9q34.1 22q11.2	CE-LPH 007
	BCR/ABL (ABL1) *Plus* Translocation, Dual Fusion Probe	CML, AML, ALL	9q34.1 22q11.2	CE-LPH 038
	CBFB Breakapart Probe	AML	16q22	CE-LPH 089
	CBFβ (CBFB)/MYH11 Translocation, Dual Fusion Probe	AML	16q22 / 16p13.1	CE-LPH 022
	CKS1B/CDKN2C (P18) Amplification/ Deletion Probe	MM	1q21-q22 / 1p32.3	CE-LPH 039
	Del(5q) Deletion Probe	AML, MDS	5q31.2 / 5p15.3	CE-LPH 024
	Del(7q) Deletion Probe	AML, MDS	7q22 / 7q31.2	CE-LPH 025
	Del(20q) Deletion Probe	MDS	20q12 / 20q13.1	CE-LPH 020
	EVI1 (MECOM) Breakapart Probe	AML, MDS	3q26.2	CE-LPH 036
	FAST PML/RARα (RARA) Translocation, Dual Fusion Probe	AML	15q24 17q21.1-q21.2	CE-LPH 064
	IGH/MAF *Plus* v2 Translocation, Dual Fusion Probe	MM	14q32.3 16q23	CE-LPH 108
	MLL (KMT2A) Breakapart Probe	ALL, AML, MDS	11q23.3	CE-LPH 013
	P53 (TP53)/ATM Combination Deletion Probe	CLL	17p13 / 11q22.3	CE-LPH 052
Prenatal conditions	New *FAST* FISH Prenatal Enumeration Probe Kit	Turner, Patau Edwards and Down syndrome	Xp11.1 -q11.1 Yp11.1 -q11.1 18p11.1 -q11.1 13q14.2 / 21q22.1	CE-LPF 001
	New Prenatal Enumeration Probe Kit	Turner, Patau Edwards and Down syndrome	Xp11.1 -q11.1 Yp11.1 -q11.1 18p11.1 -q11.1 13q14.2 / 21q22.1	CE-LPA 001
	Prenatal 13 and 21 Enumeration Probe Kit	Down and Patau syndrome	13q14.2 / 21q22.1	CE-LPA 003

A Comprehensive IVDR Portfolio

By the 31 December 2028 IVDR deadline, we are committed to certifying our entire CytoCell IVDD portfolio. This includes:

Disease Type	Disease Focus	Number of CytoCell IVDD & IVDR Probes
Haematological Malignancies	ALL	21
	AML	15
	APL	2
	CLL	15
	CML	3
	Lymphoma	17
	MDS	7
	MM	17
	MPN	2
Solid Tumour	Breast	9
	Central Nervous System	6
	Digestive System	5
	Endocrine Organs	1
	Female Reproductive Organs	5
	Head and Neck	3
	Lung, Pleura, Thymus & Heart	12
	Lymphoma	15
	Male Genital Organs	3
	Soft Tissue & Bone	12
Constitutional	Prenatal	8
	Microdeletion	14
	Satellites	50
	Subtelomere	41

Ordering information

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