

**XCyting
DNA FISH
Probes**

Our Portfolio of
IVDR-Certified
Products
April 2024



**IVDR
CERTIFIED
FISH PROBES**

THE IVDR IS EFFECTIVE AND

The IVDR Is Mandatory

On 26 May 2022, the new In Vitro Diagnostic Medical Devices Regulation (IVDR - Regulation (EU) 2017/746) became effective and replaced the previous In Vitro Diagnostic Medical Devices Directive (IVDD - Directive 98/79/EC) in the European Union.

Important changes in the new regulation include the extension of the scope of IVD devices, a new risk-based classification system (Class A to D), and the introduction of a unique device identification number (UDI).

The IVDR is the current regulatory basis for the marketing, supply, and commissioning of in vitro diagnostic medical devices on the European market (EU). The IVDR not only applies to the placing on the market of new products but also to CE-marked products under the IVDD.

A progressive roll-out of the new IVDR was decided for existing products. This means that for products, for which compliance has been declared before May 26, 2022, and which fall into Class B to D under the IVDR and require a notified body for CE certification, the transitional deadlines have been prolonged.

Under consideration of these provisions, and decided on a well-thought-out strategy, we are consecutively preparing the CE certification process for our products in accordance with the IVDR.

On the next page, you can read about our strategy for IVDR certification of our XCyting FISH Probes and our successes to date.

OUR PROBES STAY THE SAME!

Over 50 XCyting FISH Probes Are IVDR-Certified

We have already CE-certified over 50 XCyting FISH Probes under the IVDR and are working continuously to increase the IVDR-certified portfolio.

Our priority is to give you and your laboratory a smooth transition into the IVDR. Although regulations of the European Union have changed, our high production and quality standards have remained the same as our established production processes met the requirements of the IVDR straight away.

This ensures that our XCyting FISH Probes remain unchanged during the transition to the IVDR. Consequently, sample preparation and hybridization protocols remain unchanged, eliminat-

ing the need for time-consuming revalidations on your part.

To keep ordering as smooth as possible, order numbers also remain unchanged. Until further notice, we deliver CE-marked products under the IVDD, even if the products have already received CE certification in accordance with the IVDR by a notified body.

This customer-centered strategy allows you to order regulatory-compliant probes at any time and leave the IVDR transition schedule to us. On the following pages, you will find more information and an overview of the current state of IVDR-certified XCyting FISH Probes.

Briefly Noted

- Up to now, over 50 XCyting FISH Probes are CE-certified under the IVDR by a notified body.
- We prepare a smooth transition into the IVDR era for you.
- Order numbers of our XCyting FISH Probes stay the same.
- Quality standards of our XCyting FISH Probes stay the same. No revalidations are needed.
- Until further notice, we deliver CE-marked products under the IVDD, even if the products have already received CE certification in accordance with the IVDR.



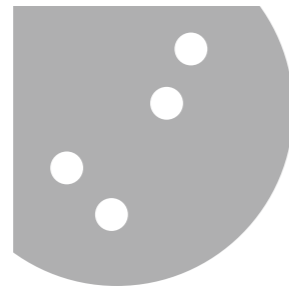
SUPPORT IS OUR PASSION AND

THAT IS YOUR ADVANTAGE!

Science

Are you searching for literature on the application or diagnostic use of a specific FISH probe?

Our team of highly qualified scientists will assist you in finding the most interesting publications.



Application

Do you have a technical issue with the preparation of your FISH?

Get in touch with us. Our experienced lab team will help you to ensure the optimal use of our products.

Regulations

Are you experiencing difficulties with the transition to the IVDR?

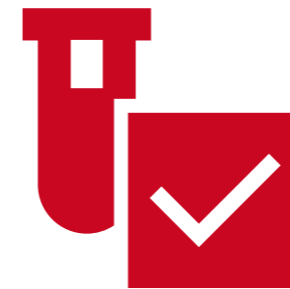
Our team of experts with expertise in regulatory affairs and quality management will answer your questions.



Portfolio

Are you unsure which FISH probe suits your clinical purpose best?

Ask our motivated sales team. Skilled colleagues will support you in making a well-informed choice.



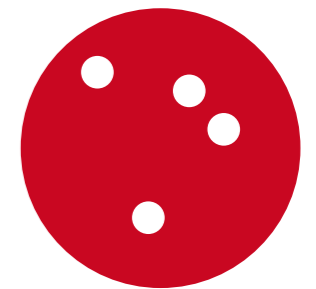
Ready-To-Use

Our XCyting FISH Probes can be used straight out of the package, as no tedious dilution steps are required for the preparation of your FISH. In this way, you can save time on one hand and minimize mixing errors on the other hand.



Work Efficiently

We put great emphasis on a simple and straightforward sample preparation and hybridization protocol. This approach is designed to guarantee rapid and consistent results, which ensures efficiency and reliability.



Simple Evaluation

The production process of our XCyting FISH Probes is designed to reduce background and artifacts in FISH samples. The improved signal-to-noise ratio with bright, well-defined signals and low background eases the interpretation of your FISH.



OUR IVDR- CERTIFIED PORTFOLIO

APRIL 2024

XL Locus-Specific Break-Apart Probes

| Product Name | Order Number | Clinical Applications |
|------------------------|---------------|-----------------------|
| XL FGFR1 | D-5041-100-OG | MLN-TK, ALL, AML |
| XL MECOM 3q26 | D-5059-100-OG | AML, CML, MDS |
| XL MLL plus | D-5060-100-OG | ALL, AML |
| XL NUP98 | D-5077-100-OG | AML, MDS |
| XL RARA BA | D-5087-100-OG | APL |
| XL KMT2A BA | D-5090-100-OG | ALL, AML |
| XL RUNX1 | D-5096-100-OG | ALL, AML |
| XL JAK2 BA | D-5098-100-OG | ALL, MLN-TK |
| XL TCL1 BA | D-5142-100-OG | T-PLL |
| XL MYC BA | D-6023-100-OG | CLL, MM, NHL |
| XL MYC BA triple-color | D-6030-100-TC | CLL, MM, NHL |

XL Locus-Specific Deletion Probes

| Product Name | Order Number | Clinical Applications |
|--|---------------|---|
| XL 6q21/6q23 | D-5039-100-OG | ALL, CLL, NHL, T-/NK-LGL |
| XL 5q31/5q33 | D-5042-100-OG | AML, MDS |
| XL CLL Probe Kit (XL DLEU/LAMP/12cen + XL ATM/TP53) | D-5044-100-TC | ALL, AML, CLL, MDS, MM, NHL, T-PLL |
| XL ATM/TP53 | D-5046-100-OG | ALL, AML, CLL, MDS, MM, NHL, T-PLL |
| XL CDKN2A | D-5053-100-OG | ALL, NHL |
| XL DLEU/LAMP | D-5054-100-OG | CLL, MM, NHL |
| XL DLEU/LAMP/12cen | D-5055-100-TC | CLL, NHL |
| XL DLEU/TP53 | D-5067-100-OG | ALL, AML, CLL, MDS, MM, NHL |
| XL RB1/DLEU/LAMP | D-5070-100-TC | CLL, MM, NHL |
| XL 5q31/5q33/5p15 | D-5081-100-TC | AML, MDS |
| XL del(5)(q31) | D-5085-100-OG | AML, MDS |
| XL 6q21/6q23/6cen | D-5088-100-TC | ALL, CLL, NHL, T-/NK-LGL |
| XL TP53/NF1 | D-5089-100-OG | ALL, AML, CLL, CMML, CML, MDS, MM, MPN, NHL |
| XL del(5)(q33) | D-5091-100-OG | AML, MDS |
| XL ATM/11cen | D-5102-100-OG | CLL, T-PLL, NHL |
| XL TP53/17cen | D-5103-100-OG | ALL, AML, CLL, MDS, MM, NHL |
| XL del(20q) plus | D-5119-100-OG | AML, MDS, MDS/MPN, MPN |
| XL 20q12/20qter plus | D-5121-100-OG | AML, MDS, MDS/MPN, MPN |
| XL 20q12/20qter/8cen plus | D-5122-100-TC | AML, MDS, MDS/MPN, MPN |
| XL 19p/19q del | D-6019-100-OG | Solid tumors, CLL, MM, MPN |

XL Locus-Specific Enumeration Probes

| Product Name | Order Number | Clinical Applications |
|----------------------------------|---------------|-----------------------|
| XL MDM2 | D-5047-100-OG | CLL |
| XL 5p15/9q22/15q22 Hyperdiploidy | D-5095-100-TC | MM |
| XL CDKN2C/CKS1B | D-5099-100-OG | MM |

XL Locus-Specific Dual Fusion Probes

| Product Name | Order Number | Clinical Applications |
|--------------------------|---------------|-----------------------|
| XL BCR/ABL1 plus | D-5052-100-OG | ALL, AML, CML/MPN |
| XL BCR/ABL1/ASS | D-5082-100-TC | ALL, AML, CML/MPN |
| XL t(15;17) DF | D-5086-100-OG | APL |
| XL t(6;9) DEK/NUP214 | D-5097-100-OG | AML |
| XL t(14;20) IGH/MAFB DF | D-5105-100-OG | MM |
| XL t(4;14) FGFR3/IGH DF | D-5108-100-OG | MM |
| XL t(14;16) IGH/MAF DF | D-5112-100-OG | MM |
| XL t(14;18) IGH/BCL2 DF | D-5113-100-OG | CLL, NHL |
| XL t(8;21) plus | D-5114-100-OG | AML |
| XL t(8;9) PCM1/JAK2 DF | D-5120-100-OG | MLN-TK, ALL, AML |
| XL t(3;3) GATA2/MECOM DF | D-5124-100-OG | AML, CML, MDS |
| XL t(11;14) CCND1/IGH DF | D-5140-100-OG | CLL, MM, NHL |
| XL t(5;11) NSD1/NUP98 DF | D-5141-100-OG | AML |
| XL CCND3/IGH DF | D-5147-100-OG | MM |

XL Locus-Specific Centromere Enumeration Probes

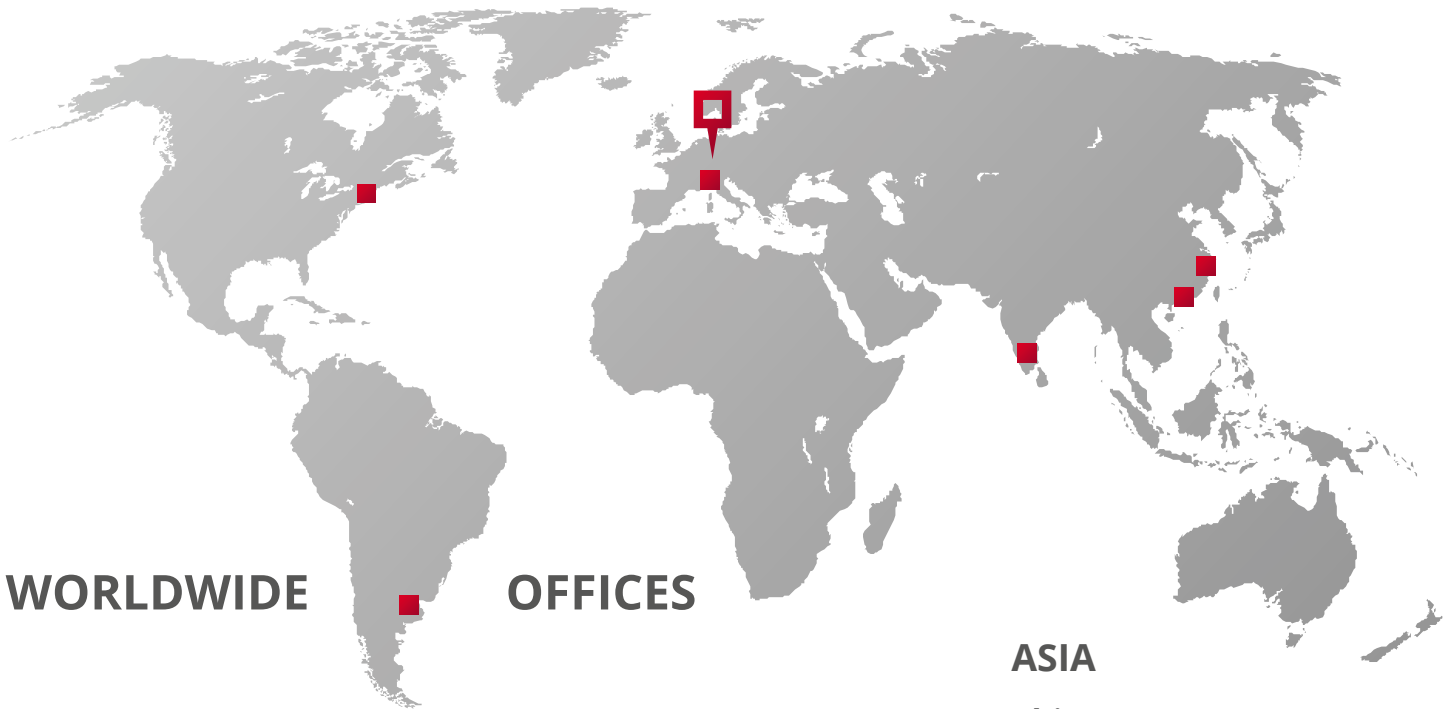
| Product Name | Order Number | Clinical Applications |
|--------------|---------------|----------------------------------|
| XCE 8 Orange | D-0808-050-OR | AML, CMML, CML/MPN, MDS, MDS/MPN |
| XCE 8 Green | D-0808-050-FI | AML, CMML, CML/MPN, MDS, MDS/MPN |
| XCE 8 Blue | D-0808-050-BL | AML, CMML, CML/MPN, MDS, MDS/MPN |

MetaSystems Probes Is Your Trusted Partner In Terms Of FISH Probes!

Comprehensive portfolio of IVDR-certified probes for future-oriented diagnostics.
Discover all IVDR-certified products of MetaSystems Probes:

www.metasytems-probes.com or scan the QR code.





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All our CE-IVD labeled MetaSystems Human FISH probe products were lawfully placed on the market before the date of application of the IVDR (Regulation (EU) 2017/746) in May 2022 on the basis of a valid certificate according to the IVDD (Directive 98/79/EC). They are still available on the market according to their IVDD classification. We assure you that the delivered products for in vitro diagnostics always comply with the respective applicable requirements of the IVDR. The specified transition periods are applied (Article 110 of the IVDR). CE-IVD products may not be available in all markets outside the EU due to varying regulatory requirements.

About MetaSystems Probes

MetaSystems Probes GmbH is a manufacturer of in vitro diagnostics in the field of fluorescence-labeled DNA probes and related products for diagnostics and research. We are distinguished above all by our excellent reputation for the quality and reliability of our products. Since 1998, we have been committed to manufacturing high-quality DNA FISH probes and operate worldwide from our headquarters near Heidelberg in Germany. Our product portfolio is constantly expanding and has now grown to over 400 DNA FISH probes and related reagents.

CONTACT US

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