



## KONFORMITÄTSERKLÄRUNG

nach Art. 5 (5) der EU-Verordnung über *In-vitro*-Diagnostika (EU) 2017/746 (IVDR)  
zur Eigenherstellung von IVDs in Gesundheitseinrichtungen

Wir erklären in alleiniger Verantwortung, dass die im Anhang aufgeführten Produkte, welche von uns hergestellt werden, allen Anforderungen der IVD-Verordnung (EU) 2017/746, entsprechend dem Anhang I, den grundlegenden Sicherheits- und Leistungsanforderungen entsprechen, die anwendbar sind. Die Produkte wurden in unseren eigenen Räumlichkeiten, im nicht industriellen Maßstab gefertigt und werden ausschließlich in unserer Gesundheitseinrichtung verwendet.

### Produktbezeichnung:

Informationen zu den verwendeten hausintern hergestellten Produkten (auch laboratory developed tests genannt, LDTs), sind der Tabelle unten zu entnehmen.

### Gesundheitseinrichtung:

MLL MVZ GmbH

in Kooperation mit MLL Münchner Leukämielabor GmbH und MLL Dx GmbH

Max-Lebsche-Platz 31

81377 München

### Produktklassifizierung nach Anhang VIII:

Klasse C

Ort, Datum:

München, 26.05.2024

Geschäftsführer:

  
\_\_\_\_\_

Leitung Qualitätsmanagement:

  
\_\_\_\_\_



## Produkte:

<b>Molekulargenetik</b>		
<b>Generische Produktgruppe (EMDN + IVP)</b>	<b>Sub-Group</b>	<b>Produkt Name</b>
W0106 + IVP3011	Qualitative PCR	BCR-ABL1_Cross_Multiplex_PCR
W0106 + IVP3011	Qualitative PCR	BCR-ABL1_Maurer_p210_PCR
W0106 + IVP3011	Qualitative PCR	BCR-ABL1_Maurer_p210_PCR_nested
W0106 + IVP3011	Qualitative PCR	BCR-ABL1_Maurer_p190_PCR
W0106 + IVP3011	Qualitative PCR	BCR-ABL1_Maurer_p190_PCR_nested
W0106 + IVP3011	Qualitative PCR	BCR-FGFR1_PCR
W0106 + IVP3011	Qualitative PCR	CBFB-MYH11_PCR
W0106 + IVP3011	Qualitative PCR	CBFB-MYH11_PCR_nested
W0106 + IVP3011	Qualitative PCR	DEK-NUP214_PCR
W0106 + IVP3011	Qualitative PCR	EP300-ZNF384_PCR
W0106 + IVP3011	Qualitative PCR	ETV6-ABL1_PCR
W0106 + IVP3011	Qualitative PCR	ETV6-MECOM_PCR
W0106 + IVP3011	Qualitative PCR	ETV6-MECOM_PCR_nested
W0106 + IVP3011	Qualitative PCR	ETV6-PDGFRB_PCR_nested
W0106 + IVP3011	Qualitative PCR	ETV6-RUNX1_PCR
W0106 + IVP3011	Qualitative PCR	ETV6-RUNX1_PCR_nested
W0106 + IVP3011	Qualitative PCR	FIP1L1-PDGFRB_PCR_nested
W0106 + IVP3011	Qualitative PCR	H4-PDGFRB_PCR_nested
W0106 + IVP3011	Qualitative PCR	IGH-BCL2_PCR
W0106 + IVP3011	Qualitative PCR	IGH-CCND1_PCR
W0106 + IVP3011	Qualitative PCR	KMT2A-AFF1_PCR
W0106 + IVP3011	Qualitative PCR	KMT2A-AFF1_PCR_nested
W0106 + IVP3011	Qualitative PCR	KMT2A-ARHGEF12_PCR
W0106 + IVP3011	Qualitative PCR	KMT2A-CBL_PCR
W0106 + IVP3011	Qualitative PCR	KMT2A-ELL_PCR
W0106 + IVP3011	Qualitative PCR	KMT2A-MLLT1_PCR
W0106 + IVP3011	Qualitative PCR	KMT2A-MLLT1 Exon6_PCR
W0106 + IVP3011	Qualitative PCR	KMT2A-MLLT10_PCR
W0106 + IVP3011	Qualitative PCR	KMT2A-MLLT3_PCR
W0106 + IVP3011	Qualitative PCR	KMT2A-MLLT3_PCR_nested
W0106 + IVP3011	Qualitative PCR	KMT2A-MLLT3 AF9AS2_PCR
W0106 + IVP3011	Qualitative PCR	KMT2A-MLLT4_PCR
W0106 + IVP3011	Qualitative PCR	KMT2A-SEPT5_PCR_nested
W0106 + IVP3011	Qualitative PCR	KAT6A-CREBBP
W0106 + IVP3011	Qualitative PCR	NPM1-MLF1_PCR
W0106 + IVP3011	Qualitative PCR	NUP214-ABL1_PCR

W0106 + IVP3011	Qualitative PCR	NUP98-NSD1_PCR
W0106 + IVP3011	Qualitative PCR	PCM1-JAK2_PCR
W0106 + IVP3011	Qualitative PCR	PCM1-JAK2_PCR_nested
W0106 + IVP3011	Qualitative PCR	PICALM-MLLT10_PCR
W0106 + IVP3011	Qualitative PCR	PICALM-MLLT10_PCR_nested
W0106 + IVP3011	Qualitative PCR	PML-RARA_PCR_nested
W0106 + IVP3011	Qualitative PCR	RUNX1-MECOM_PCR_nested
W0106 + IVP3011	Qualitative PCR	RUNX1-RUNX1T1_PCR
W0106 + IVP3011	Qualitative PCR	SET-NUP214_PCR
W0106 + IVP3011	Qualitative PCR	SET-NUP214_PCR_nested
W0106 + IVP3011	Qualitative PCR	STIL-TAL1_PCR
W0106 + IVP3011	Qualitative PCR	STIL-TAL1_PCR_nested
W0106 + IVP3011	Qualitative PCR	TCF3-HLF_PCR
W0106 + IVP3011	Qualitative PCR	TCF3-PBX1_PCR
W0106 + IVP3011	Qualitative PCR	WDR48-PDGFRB_PCR
W0106 + IVP3011	Qualitative PCR	ZBTB16-RARA_PCR_nested
W0106 + IVP3011	Qualitative PCR	ZNF198-FGFR1_PCR
W0106 + IVP3011	Targeted Sequencing	ANKRD26_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	ARID1A_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	ASXL1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	ASXL2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	ATM_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	ATRX_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	BCL2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	BCOR_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	BCORL1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	BCR-ABL1 Mutation_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	BIRC3_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	BPGM_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	BRAF_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	BTK_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	CALR_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	CARD11_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	CBL_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	CCL22_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	CDKN2A_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	CEBPA_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	CREBBP_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	CRLF2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	CSF3R_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	CSNK1A1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	CUX_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	CXCR4_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	DDX41_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	DNMT3A_SQ_NAISP

W0106 + IVP3011	Targeted Sequencing	EGLN1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	EGR2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	ELANE_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	EP300_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	EPAS1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	EPO_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	EPOR_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	ETNK1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	ETV6_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	EZH2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	FBXW7_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	FLT3_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	FOXO1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	GATA1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	GATA2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	GNAS_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	HFE_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	HRAS_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	ID3_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	IDH1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	IDH2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	IKZF1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	JAK1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	JAK2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	JAK3_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	KIT_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	KLF2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	KLHL6_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	KRAS_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	MAP2K1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	MAPK1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	MEF2B_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	MPL_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	MYC_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	MYD88_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	NF1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	NFKBIE_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	NOTCH1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	NOTCH2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	NPM1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	NRAS_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	PAX5_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	PHF6_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	PIGA_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	PLCG2_SQ_NAISP

W0106 + IVP3011	Targeted Sequencing	POT1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	PPM1D_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	PRPF8_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	PTEN_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	PTPN11_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	RAD21_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	RPS15_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	RUNX1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	SAMHD1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	SETBP1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	SETD2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	SF3A1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	SF3B1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	SH2B3_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	SMC1A_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	SRSF2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	STAG2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	STAT3_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	STAT5B_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	TCF3_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	TERC_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	TERT_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	TET2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	TP53_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	U2AF1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	U2AF2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	UBA1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	UBR5_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	VHL_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	WT1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	XPO1_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	ZRSR2_SQ_NAISP
W0106 + IVP3011	Targeted Sequencing	Gen-Panel_ "Familiäre Erythrozytose" _MLLv1
W0106 + IVP3011	Targeted Sequencing	Gen-Panel_ "Lymphatische Erkrankungen" _MLLv2
W0106 + IVP3011	Targeted Sequencing	Gen-Panel_ "Myeloische Erkrankungen" _MLLv2
W0106 + IVP3011	Targeted Sequencing	Gen-Panel_ "TSO500"
W0106 + IVP3011	Targeted Sequencing	Gen-Panel_ "Hämoglobinopathie" _MLLv1
W0106 + IVP3011	Targeted Sequencing	TP53_SQ_CNV_CN_LOH
W0106 + IVP3011	Exome Sequencing	Gen-Panel "WES" IDT xGen Exome v2
W0106 + IVP3011	Exome Sequencing	TruSeq-DNA-Nano_IDT-xGen-Exome-v2_WES
W0106 + IVP3011	Genome Sequencing	TruSeq-DNA-PCR-Free_WGS
W0106 + IVP3011	Genome Sequencing	TruSeq-DNA-Nano_WGS

W0106 + IVP3011	Transcriptome Sequencing	ILMN-Stranded-Total-RNA_WTS
W0106 + IVP3011	Transcriptome Sequencing	NEB-Next-UltraII-Directional-RNA_WTS
W0106 + IVP3011	Fragment Analysis	AMLplex
W0106 + IVP3011	Fragment Analysis	BCR_FA
W0106 + IVP3011	Fragment Analysis	FLT3-ITD_FA_cDNA
W0106 + IVP3011	Fragment Analysis	FLT3-ITD_FA_DNA
W0106 + IVP3011	Fragment Analysis	IGHV_FA_cDNA
W0106 + IVP3011	Fragment Analysis	IGHV_FA_DNA
W0106 + IVP3011	Fragment Analysis	IKZF1_FA
W0106 + IVP3011	Fragment Analysis	NPM1_FA_cDNA
W0106 + IVP3011	Fragment Analysis	NPM1_FA_DNA
W0106 + IVP3011	Fragment Analysis	TCR_FA
W0106 + IVP3011	Quantitative PCR	TP53_ddPCR
W0106 + IVP3011	Quantitative PCR	TPSAB1_ddPCR
W0106 + IVP3011	Quantitative PCR	SF3B1_ddPCR
W0106 + IVP3011	Quantitative PCR	KIT_ddPCR
W0106 + IVP3011	Quantitative PCR	IDH2_ddPCR
W0106 + IVP3011	Quantitative PCR	IDH1_ddPCR
W0106 + IVP3011	Quantitative PCR	FLT3_ddPCR
W0106 + IVP3011	Quantitative PCR	DNMT3A_ddPCR
W0106 + IVP3011	Quantitative PCR	NPM1_rare_ddPCR
W0106 + IVP3011	Quantitative PCR	BCR-ABL_P190_RQ-PCR
W0106 + IVP3011	Quantitative PCR	BCR-ABL_P210_RQ-PCR
W0106 + IVP3011	Quantitative PCR	BCR-ABL_P230_RQ-PCR
W0106 + IVP3011	Quantitative PCR	BCR-ABLe16a2_RQ-PCR
W0106 + IVP3011	Quantitative PCR	BCR-ABLe4a2_RQ-PCR
W0106 + IVP3011	Quantitative PCR	BCR-ABLe6a2_RQ-PCR
W0106 + IVP3011	Quantitative PCR	BCR-ABLe8a2_RQ-PCR
W0106 + IVP3011	Quantitative PCR	BRAFV600E_RQ-PCR
W0106 + IVP3011	Quantitative PCR	CBFB-MYH11_RQ-PCR
W0106 + IVP3011	Quantitative PCR	CRLF2_RQ-PCR
W0106 + IVP3011	Quantitative PCR	CyclinD1_RQ-PCR
W0106 + IVP3011	Quantitative PCR	DEK-NUP214_RQ-PCR
W0106 + IVP3011	Quantitative PCR	ETV6-ABL1_RQ-PCR
W0106 + IVP3011	Quantitative PCR	ETV6-RUNX1_RQ-PCR
W0106 + IVP3011	Quantitative PCR	IGH-BCL2_RQ-PCR
W0106 + IVP3011	Quantitative PCR	IKZF1_RQ-PCR
W0106 + IVP3011	Quantitative PCR	JAK2V617F_RQ-PCR
W0106 + IVP3011	Quantitative PCR	JAK2V617F_DNA_RQ-PCR
W0106 + IVP3011	Quantitative PCR	KITD816V_RQ-PCR_DNA
W0106 + IVP3011	Quantitative PCR	KITD816V_RQ-PCR_cDNA
W0106 + IVP3011	Quantitative PCR	KMT2A-AFF1_RQ-PCR
W0106 + IVP3011	Quantitative PCR	KMT2A-ELL_RQ-PCR
W0106 + IVP3011	Quantitative PCR	KMT2A-MLLT1_RQ-PCR

W0106 + IVP3011	Quantitative PCR	KMT2A-MLLT10_RQ-PCR
W0106 + IVP3011	Quantitative PCR	KMT2A-MLLT3_RQ-PCR
W0106 + IVP3011	Quantitative PCR	KMT2A-MLLT4_RQ-PCR
W0106 + IVP3011	Quantitative PCR	KMT2A-MLLT6_RQ-PCR
W0106 + IVP3011	Quantitative PCR	KMT2A-PTD_RQ-PCR
W0106 + IVP3011	Quantitative PCR	MECOM_RQ-PCR
W0106 + IVP3011	Quantitative PCR	MYD88L265P_RQ-PCR
W0106 + IVP3011	Quantitative PCR	NPM1_RQ-PCR
W0106 + IVP3011	Quantitative PCR	NUP214-ABL1_RQ-PCR
W0106 + IVP3011	Quantitative PCR	NUP98-NSD1_RQ-PCR
W0106 + IVP3011	Quantitative PCR	PDGFRA_RQ-PCR
W0106 + IVP3011	Quantitative PCR	PDGFRB_RQ-PCR
W0106 + IVP3011	Quantitative PCR	PML-RARA_bcr1_RQ-PCR_FAST
W0106 + IVP3011	Quantitative PCR	PML-RARA_bcr1_RQ-PCR
W0106 + IVP3011	Quantitative PCR	PML-RARA_bcr3_RQ-PCR_FAST
W0106 + IVP3011	Quantitative PCR	PML-RARA_bcr3_RQ-PCR
W0106 + IVP3011	Quantitative PCR	RUNX1-RUNX1T1_RQ-PCR
W0106 + IVP3011	Quantitative PCR	SOX11_RQ-PCR
W0106 + IVP3011	Quantitative PCR	TCF3-PBX1_RQ-PCR
W0106 + IVP3011	Quantitative PCR	TCR-MRD_RQ-PCR
W0106 + IVP3011	Quantitative PCR	BCR-MRD_RQ-PCR
W0106 + IVP3011	Quantitative PCR	WT1_RQ-PCR
W0106 + IVP3011	Quantitative PCR	ZBTB16-RARA_RQ-PCR

### Zytogenetik

Generische Produktgruppe (EMDN + IVP)	Sub-Group	Produkt Name
W0106 + IVP3004	Chromosome Analysis	Chromosome analysis
W0106 + IVP3004	FISH	Fluorescence in situ hybridization (FISH)

### Immunphänotypisierung

Generische Produktgruppe (EMDN + IVP)	Sub-Group	Produkt Name
W0103 + IVP 3006	-	CLL/B-NHL_Panel_I
W0103 + IVP 3006	-	T-NHL_Panel_I
W0103 + IVP 3006	-	AML,MPN_Panel_I
W0103 + IVP 3006	-	ALL_Panel_I
W0103 + IVP 3006	-	Multiple Myeloma/Pla_Panel_I
W0103 + IVP 3006	-	PNH_Panel_I
W0103 + IVP 3006	-	MDS_Panel_I
W0103 + IVP 3006	-	Spherocytosis_Panel_I
W0103 + IVP 3006	-	Mastocytosis_Panel_I