

Manufacturer's Declaration of Conformity

Date of issue: 10 May 2022

Kreatech Biotechnology B.V.

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The Netherlands

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This is a declaration made in accordance with the requirements of
*Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 in
In Vitro Medical Devices* and the applicable Harmonized Standards.

And is relating to the following products
Kreatech FISH Probes; Hematology; Solid Tumor DNA Probes
See attachment for the identifying information for all the products.

The Manufacturer of the Products covered by this Declaration is
Kreatech Biotechnology B.V.
Vlierweg 20
1032LG Amsterdam
The Netherlands

The classification of the devices covered by this Declaration is as follows
Non Annex II General IVD : IVD, Annex III

KREATECH Biotechnology B.V. is certified by BSI 2797 for
ISO 13485:2016 Certificate – MD 724144
European In Vitro Diagnostic Medical Devices Directive Annex IV certificate CE 724142

Each listed IVD medical device related to this declaration complies with the applicable classification rules and essential principles of the Directive, at each stage from the design of the device until its final inspection before being supplied. This declaration is being made on the basis of the above mentioned certificates.

Amsterdam,



Herman H. Volkers, COO
Kreatech Biotechnology B.V.



Gilles Westerhof, QRA Manager
Kreatech Biotechnology B.V.

This declaration is valid from 13 May 2022 to 25 May 2026.

Kreatech FISH Probes, Hematology DNA Probes Non Annex II General IVD			
Cat no.	Product name	No. of tests	GMDN code
KBI-10003	FIP1L1 / CHIC2 / PDGFRA (4q12) Deletion, Break	10	61199
KBI-10004	PDGFRB (5q32) Break	10	61199
KBI-10005	BCR/ABL1 t(9;22) Fusion	10	61199
KBI-10006	BCR/ABL1 t(9;22) Triple-Color, Dual-Fusion	10	61199
KBI-10007	FIP1L1 / CHIC2 / PDGFRA (4q12) Deletion, Break, Triple-Color	10	61199
KBI-10008	BCR/ABL1 t(9;22) Dual-Color, Single-Fusion, Extra Signal	10	61199
KBI-10011	TP53 (17p13) / MPO (17q22) "ISO 17q"	10	61199
KBI-10102	DLEU1 (13q14) / 13qter	10	61199
KBI-10103	ATM (11q22) / SE 11	10	61199
KBI-10106	MYC (8q24) / SE 8	10	61199
KBI-10108	ATM (11q22) / GLI1 (12q13)	10	61199
KBI-10112	TP53 (17p13) / SE 17	10	61199
KBI-10113	DLEU1 (13q14) / TP53 (17p13)	10	61199
KBI-10114	TP53 (17p13) / ATM (11q22)	10	61199
KBI-10117	6q21 / MYC (8q24)	10	61199
KBI-10202	7q- (7q22; 7q36)	10	61199
KBI-10203	20q- (20q12) / 20q11	10	61199
KBI-10204	MECOM t(3;3); inv(3) (3q26) Break	10	61199
KBI-10205	MECOM t(3;3); inv(3) (3q26) Break, Triple-Color	10	61199
KBI-10207	7q- (7q22; 7q36) / SE7 Triple-Color	10	61199
KBI-10209	5q- (5q31; 5q33)	10	61199
KBI-10210	5q- (5q31; 5q33) / TERT (5p15) Triple-Color	10	61199
KBI-10302	PML/RARA t(15;17) Fusion	10	61199
KBI-10303	KMT2A (11q23) Break	10	61199
KBI-10305	RARA (17q21) Break	10	61199
KBI-10307	KMT2A/MLLT1 t(11;19) Fusion	10	61199
KBI-10308	KMT2A/MLLT3 t(9;11) Fusion	10	61199
KBI-10309	KMT2A/MLLT4 t(6;11) Fusion	10	61199
KBI-10401	ETV6/RUNX1 t(12;21) Fusion	10	61199
KBI-10403	ETV6 (12p13) Break	10	61199
KBI-10404	KMT2A/AFF1 t(4;11) Fusion	10	61199
KBI-10507	1q21 / SRD (1p36)	10	61199
KBI-10508	15q22 / 9q34	10	61199
KBI-10509	19q13 / TP53 (17p13)	10	61199
KBI-10510	MAFB/IGH t(14;20) Fusion	10	61199
KBI-10601	IGH (14q32) Break	10	61199
KBI-10602	FGFR3/IGH t(4;14) Fusion	10	61199
KBI-10603	MYC/IGH t(8;14) Fusion	10	61199
KBI-10604	CCND1/IGH t(11;14) Fusion	10	61199
KBI-10605	MYEOV/IGH t(11;14) Fusion	10	61199
KBI-10606	BCL2/IGH t(14;18) Fusion	10	61199
KBI-10607	BCL6 (3q27) Break	10	61199
KBI-10609	CCND1 (11q13) Break	10	61199
KBI-10610	MAF/IGH t(14;16) Fusion	10	61199
KBI-10611	MYC (8q24), Triple-Color, Break	10	61199
KBI-10612	BCL2 (18q21) Break	10	61199
KBI-12302	PML/RARA t(15;17) Fusion	20	61199
KBI-12005	BCR/ABL1 t(9;22) Fusion	20	61199

Kreatech FISH Probes, Solid tumor DNA Probes Non Annex II General IVD			
Prod. no.	Product name	No. of tests	GMDN code
KBI-00116	MAF (16q23) / D16Z3	10	61199
KBI-10701	ERBB2 (17q12) / SE 17	10	61199
KBI-10702	EGFR (7p11) / SE 7	10	61199
KBI-10706	MYCN (2p24) / AFF3 (2q11)	10	61199
KBI-10713	SS18 (18q11) Break	10	61199
KBI-10714	DDIT3 (12q13) Break	10	61199
KBI-10715	FUS (16p11) Break	10	61199
KBI-10716	FOXO1 (13q14) Break	10	61199
KBI-10717	MDM2 (12q15) / SE 12	10	61199
KBI-10719	MET (7q31) / SE 7	10	61199
KBI-10729	IGH (14q32) Break (tissue)	10	61199
KBI-10730	BCL6 (3q27) Break (tissue)	10	61199
KBI-10737	FGFR1 (8p11) Break	10	61199
KBI-10738	TP53 (17p13) / SE 17 (tissue)	10	61199
KBI-10742	COL1A1/PDGFB t(17;22) Dual-Color, Single-Fusion	10	61199
KBI-10745	BCL2 (18q21) Break (tissue)	10	61199
KBI-10746	ALK (2p23) / EML4 t(2;2) inv (2) Fusion	10	61199
KBI-10747	ALK (2p23) Break	10	61199
KBI-10749	MYC (8q24) Triple-Color, Break (tissue)	10	61199
KBI-10750	EWSR1 (22q12) Break	10	61199
KBI-10751	EWSR1/NFATC2 t(20;22) Dual-Color, Single-Fusion	10	61199
KBI-10752	ROS1 (6q22) Break	10	61199
KBI-10753	RET (10q11) Break	10	61199
KBI-10755	BCL2/IGH t(14;18) Fusion (tissue)	10	61199
KBI-12112	TP53 (17p13) / SE 17	20	61199
KBI-12754	FGFR1 (8p11) / SE 8	20	61199
KBI-14701	ERBB2 (17q12) / SE 17	50	61199

Kreatech FISH Probes, Solid tumor DNA Probes Non Annex II General IVD			
Prod. no.	Product name	No. of tests	GMDN code
KBI-XL001	ALK (2p23) Break – XL for BOND	40	61199
KBI-XL002	ROS1 (6q22) Break – XL for BOND	40	61199
KBI-XL003	MET (7q31) / SE 7 (D7Z1) – XL for BOND	40	61199
KBI-XL004	FGFR1 (8p11) / SE 8 (D8Z1) – XL for BOND	40	61199
KBI-XL005	RET (10q11) Break – XL for BOND	40	61199
KBI-XL006	MYC (8q24) Break – XL for BOND	40	61199
KBI-XL007	IGH (14q32) Break – XL for BOND	40	61199
KBI-XL008	BCL2 (18q21) Break – XL for BOND	40	61199
KBI-XL009	BCL6 (3q27) Break – XL for BOND	40	61199
KBI-XL010	TP53 (17p13) / SE 17 – XL for BOND	40	61199
KBI-XL011	EGFR (7p11) / SE7 (D7Z1) – XL for BOND	40	61199
KBI-XL012	NTRK1 (1q23) Break – XL for BOND	40	61199
KBI-XL013	CCND1 (11q13) Break – XL for BOND	40	61199
KBI-XL014	MDM2 (12q15) / SE 12 (D12Z3) – XL for BOND	40	61199
KBI-XL015	DDIT3 (12q13) Break – XL for BOND	40	61199
KBI-XL016	FOXO1 (13q14) Break – XL for BOND	40	61199
KBI-XL017	FUS (16p11) Break – XL for BOND	40	61199
KBI-XL018	SS18 (18q11) Break – XL for BOND	40	61199
KBI-XL019	EWSR1 (22q12) Break – XL for BOND	40	61199
KBI-XL020	ERBB2 (17q12) / SE 17 (D17Z1) – XL for BOND	40	61199

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Final Audit Report

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