

Name of Manufacturer; Genmark Sağlık Ürünleri İth. İhr. ve Tic. Ltd. Şti.

Adress: Halil Rifat Paşa Mah. Güler Sok. No:51/1 34384 Şişli-İstanbul/Türkiye

Family Name; geneMAP

Competent Authority; Medicines and Medical Devices Agency of Türkiye

Conformity assessment route: In Vitro Diagnostic Medical Device Directive 98/79/EC Annex III (self declaration)

Product Classification: Other device

We, Genmark declared that the products listed below are in conformity with the essential requirements and provision of Council Directive on the harmonization of the Laws of the Member States concerning In-Vitro-Diagnostic Directive 98/79/EC in accordance with Annex III.

The object of declaration described above meets the requirements of the European Union harmonization legislation and Quality Management System ISO 13485:2016.

Basic UDI-DI	Catalog Number	Product Name	EDMA Code
B-TRMF000028405FVLRT50PC	FII-RT50	geneMAP™ FII Mutation Detection Kit	16 01 01 14
B-TRMF000028405FIIRT50H2	FVL-RT50	geneMAP™ FV Leiden Mutation Detection Kit	16 01 01 03
B-TRMF000028405FXIIIRT5M9	FXIII-RT50	geneMAP™ FXIII Mutation Detection Kit	16 01 01 16
B-TRMF000028405MTHFIRT5MU	MTHFI-RT50	geneMAP™ MTHFR C677T Mutation Detection Kit	16 01 01 16
B-TRMF000028405MTHFIIRT5N5	MTHFII-RT50	geneMAP™ MTHFR A1298C Mutation Detection Kit	16 01 01 16
B-TRMF000028405PAIRT50K4	PAI-RT50	geneMAP™ PAI-1 4G/5G Mutation Detection Kit	16 01 01 90
B-TRMF000028405THRRT50T6	THR-RT50	geneMAP™ Thrombophilia Panel (FII, FVL, MTHFR677 & MTHFR1298)	16 01 01 90
B-TRMF000028405THR6RT50HP	THR6-RT50	geneMAP™ Thrombophilia Panel (FII, FVL, MTHFR677, MTHFR1298, PAI & FXIII)	16 01 01 90
B-TRMF000028405FMF5RT506T	FMF-RT50	geneMAP™ FMF 11 Mutation Detection Kit	16 01 01 90
B-TRMF000028405FMF5RT506T	FMF.5-RT50	geneMAP™ FMF 5 Mutation Detection Kit	16 01 01 90
B-TRMF000028405SMN1MRT5J5	SMN1M-RT50	geneMAP™ SMN1 Exon7/8 Deletion Screening Kit	16 90 90 01
B-TRMF000028405B27RT50Y2	B27-RT50	geneMAP™ HLA-B*27 Detection Kit	16 01 04 90
B-TRMF000028405B51RT50X7	B51-RT50	geneMAP™ HLA-B*51 Detection Kit	16 01 04 90
B-TRMF000028405CELRT25EV	Cel-RT25	geneMAP™ Celiac (DQ2, DQ8, DR4) Detection Kit	16 01 04 90
B-TRMF000028405BCRSCRRTF7	BCRSCR-RT48	geneMAP™ BCR-ABL1 (p190, p210, p230) Screening Kit	16 02 01 08
B-TRMF000028405BCR210RTT8	BCR210-RT48	geneMAP™ BCR-ABL1 p210 (Mbc) IS-MMR Detection Kit	16 02 01 08
B-TRMF000028405BCR190RTUM	BCR190-RT48	geneMAP™ BCR-ABL1 p190 (mbc) Detection Kit	16 02 01 08
B-TRMF000028405BCR230RTTN	BCR230-RT48	geneMAP™ BCR-ABL1 p230 (µbc) Detection Kit	16 02 01 08
B-TRMF000028405AML1RT244V	AML1-RT24	geneMAP™ RUNX1-RUNX1T1 t(8;21) Detection Kit	16 02 01 90
B-TRMF000028405E2ART244S	E2A-RT24	geneMAP™ TCF3/PBX1 t(1;19) Detection Kit	16 02 01 90
B-TRMF000028405MLLRT24NY	MLL-RT24	geneMAP™ MLL-AF4 t(4;11) Detection Kit	16 02 01 90
B-TRMF000028405TELRT24PU	TEL-RT24	geneMAP™ TEL-AML1 t(12;21) Detection Kit	16 02 01 90
B-TRMF000028405CBFRT24BJ	CBF-RT24	geneMAP™ CBFβ-MYH11 Inv(16) Detection Kit	16 02 01 11
B-TRMF000028405PMLRT24QY	PML-RT24	geneMAP™ PML-RARA t(15;17) bcr1&bcr2, bcr3 Detection Kit	16 02 01 90
B-TRMF000028405NPMQRT24R9	NPMQ-RT24	geneMAP™ NPM1 (MutA, B, C&D) Mutation Detec. Kit	16 02 01 90
B-TRMF000028405FIP1RT247C	FIP1-RT24	geneMAP™ FIP1L1-PDGFRα Detection Kit	16 02 01 90
B-TRMF000028405WT1RT24NL	WT1-RT24	geneMAP™ WT1 Expression Analysis Kit	16 02 01 90
B-TRMF000028405MPLRT25QN	MPL-RT25	geneMAP™ MPL W515 A/L/K/R Mutation Detection Kit	16 02 01 90

Signature: Istanbul, Turkey 08.04.2022

Mehmet Ekti (Manager)

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Basic UDI-DI	Catalog Number	Product Name	EDMA Code
B-TRMF000028405FLT3RT25BB	FLT3-RT25	geneMAP™ FLT3 D835Y Mutation Detection Kit	16 02 01 90
B-TRMF000028405FLT3FA255Q	FLT3-FA25	geneMAP™ FLT3 ITD/D835Y Mutation Detec. Kit	16 02 01 90
B-TRMF000028405cKITRT25XK	cKIT-RT25	geneMAP™ c-KIT D816V Mutation Detection Kit	16 02 01 90
B-TRMF000028405JK12QRT5ZG	JK12Q-RT50	geneMAP™ JAK2 Exon12 Mutations Detection Kit	16 02 01 90
B-TRMF000028405MGMRT50MB	MGM-RT50	geneMAP™ MGMT Methylation Analysis Kit	16 02 01 90
B-TRMF000028405MLH1RT509V	MLH1-RT50	geneMAP™ MLH1 Methylation Analysis Kit	16 02 01 90
B-TRMF000028405PDLRT24MB	PDL-RT24	geneMAP™ PD-L1 Expression Analysis Kit	16 02 01 90
B-TRMF000028405HERRT24KJ	HER-RT24	geneMAP™ HER-2 Expression Analysis Kit	16 02 01 13
B-TRMF000028405NTRKRT24TC	NTRK-RT24	geneMAP™ NTRK Fusion Transcript Detection Kit	16 02 01 90
B-TRMF000028405MTBRT100HC	MTB-RT100	geneMAP™ MTB Detection Kit	15 01 07 40
B-TRMF000028405MTBNRT10LX	MTBN-RT100	geneMAP™ MTB/NTM Detection Kit	15 01 07 40
B-TRMF000028405MTBMDRRTNE	MTB/MDR-RT50	geneMAP™ MTB/MDR Detection Kit	15 01 07 40
B-TRMF000028405MTBXDRRTS7	MTB/XDR-RT25	geneMAP™ MTB/XDR Detection Kit	15 01 07 40
B-TRMF000028405BORRT50LF	BOR-RT50	geneMAP™ Borrelia Detection Kit	15 01 06 90
B-TRMF000028405nCoV-RT50FZ	nCoV-RT500	geneMAP™ 2019-nCoV (SARS-CoV-2) Detection Kit	15 04 09 40
B-TRMF000028405nCoV-RT50K9	nCoV-RT500	geneMAP™ 2019-nCoV Triple Detection Kit	15 04 09 40
B-TRMF000028405RV2RT100FA	RV2-RT100	geneMAP™ Respiratory Viral Panel 2 (2019-nCoV, Inf A/B, RSV A/B)	15 30 02 42
B-TRMF000028405RV3RT100FP	RV3-RT100	geneMAP™ Respiratory Viral Panel 3 (2019-nCoV, Inf A/B)	15 30 02 42
B-TRMF000028405DPYDRT25KS	DPYD-RT25	geneMAP™ DPYD Mutations Detection Kit	16 02 01 90
B-TRMF000028405MPRT50SP	MP-RT50	geneMAP™ Monkeypox PCR Detection Kit	15 04 09 40
B-TRMF000028405HPVGRT50MX	HPVG-RT50	geneMAP™ HPV HR & 6/11 Genotyping Kit	15 04 08 41
B-TRMF000028405RVMRT50W3	RM-RT50	geneMAP™ Respiratory Master Panel	15 30 04 42

Signature: **Istanbul, Turkey 08.04.2022**
Mehmet Ekti (Manager)

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ES ATITIKIMO DEKLARACIJA

Gamintojo pavadinimas; Genmark Sağlık Ürünleri İth. İhr. ve Tic. Ltd. Şti.

Adresas: Halil Rifat Paşa Mah. Güleris Sokas. Nr.: 51/1 34384 Şişli-Stambulas/ Turkija

Grupės pavadinimas: genoMAP

Kompetentinga institucija: Turkijos vaistų ir medicinos prietaisų agentūra

Atitikties vertinimo būdas: *In vitro* diagnostikos medicinos prietaisų direktyva 98/79/EB III priedas (savarankiška deklaracija)

Produkto klasifikacija: kitas įrenginys

Mes, Genmark, paskelbėme, kad toliau išvardinti gaminiai atitinka esminius Tarybos direktyvos dėl valstybių narių įstatymų, susijusių su *In vitro* diagnostikos direktyva 98/79/EB, suderinimo reikalavimus ir nuostatą pagal III priedą.

Aukščiau aprašytas deklaravimo objektas atitinka Europos Sąjungos derinimo teisės aktų ir kokybės vadybos sistemos ISO 13485:2016 reikalavimus.

Pagrindinis UDI-DI	Katalogo numeris	produkto pavadinimas	EDMA kodas
B-TRMF000028405FVLR50PC	FII-RT50	geneMAP™™ FII mutacijų aptikimo rinkinys	16 01 01 14
B-TRMF000028405FIIRT50H2	FVL-RT50	geneMAP™™ FV Leiden mutacijų aptikimo rinkinys	16 01 01 03
B-TRMF000028405FXIIIRT5M9	FXIII-RT50	geneMAP™™ FXIII mutacijų aptikimo rinkinys	16 01 01 16
B-TRMF000028405MTHFIIRT5MU	MTHFI-RT50	geneMAP™™ MTHFR C677T mutacijų aptikimo rinkinys	16 01 01 16
B-TRMF000028405MTHFIIRT5N5	MTHFII-RT50	geneMAP™™ MTHFR A1298C mutacijų aptikimo rinkinys	16 01 01 16
B-TRMF000028405PAIRT50K4	PAI-RT50	geneMAP™™ PAI-1 4G/5G mutacijų aptikimo rinkinys	16 01 01 90
B-TRMF000028405THRR50T6	THR-RT50	geneMAP™™ trombofilijos skydelis (FII, FVL, MTHFR677 ir MTHFR1298)	16 01 01 90
B-TRMF000028405THR6RT50HP	THR6-RT50	geneMAP™™ trombofilijos skydelis (FII, FVL, MTHFR677, MTHFR1298, PAI ir FXIII)	16 01 01 90
B-TRMF000028405FMF5RT506T	FMF-RT50	geneMAP™™ FMF 11 mutacijų aptikimo rinkinys	16 01 01 90
B-TRMF000028405FMF5RT506T	FMF.5-RT50	geneMAP™™ FMF 5 mutacijų aptikimo rinkinys	16 01 01 90
B-TRMF000028405SMN1MRT5J5	SMN1M-RT50	geneMAP™™ SMN1 Exon7/8 ištrynimo atrankos rinkinys	16 90 90 01
B-TRMF000028405B27RT50Y2	B27-RT50	geneMAP™™ HLA-B*27 aptikimo rinkinys	16 01 04 90
B-TRMF000028405B51RT50X7	B51-RT50	geneMAP™™ HLA-B*51 aptikimo rinkinys	16 01 04 90
B-TRMF000028405CELRT25EV	Cel-RT25	geneMAP™™ celiakijos (DQ2, DQ8, DR4) aptikimo rinkinys	16 01 04 90
B-TRMF000028405BCRSCRRTF7	BCRSCR-RT48	geneMAP™™ BCR-ABL1 (p190, p210, p230) atrankos rinkinys	16 02 01 08
B-TRMF000028405BCR210RTT8	BCR210-RT48	geneMAP™™ BCR-ABL1 p210 (Mbc) IS-MMR aptikimo rinkinys	16 02 01 08
B-TRMF000028405BCR190RTUM	BCR190-RT48	geneMAP™™ BCR-ABL1 p190 (mbcr) aptikimo rinkinys	16 02 01 08
B-TRMF000028405BCR230RTTN	BCR230-RT48	geneMAP™™ BCR-ABL1 p230 (ubcr) aptikimo rinkinys	16 02 01 08
B-TRMF000028405AML1RT244V	AML1-RT24	geneMAP™™ RUNX1-RUNX1T1 t(8;21) aptikimo rinkinys	16 02 01 90
B-TRMF000028405E2ART244S	E2A-RT24	geneMAP™™ TCF3/PBX1 t(1;19) aptikimo rinkinys	16 02 01 90
B-TRMF000028405MLLRT24NY	MLL-RT24	geneMAP™™ MLL-AF4 t(4;11) aptikimo rinkinys	16 02 01 90
B-TRMF000028405TELRT24PU	TEL-RT24	geneMAP™™ TEL-AML1 t(12;21) aptikimo rinkinys	16 02 01 90
B-TRMF000028405CBFRT24BJ	CBF-RT24	geneMAP™™ CBFβ-MYH11 Inv(16) aptikimo rinkinys	16 02 01 11
B-TRMF000028405PMLRT24QY	PML-RT24	geneMAP™™ PML-RARA (15;17) bcr1&bcr2, bcr3 aptikimo rinkinys	16 02 01 90
B-TRMF000028405NPMQRT24R9	NPMQ-RT24	geneMAP™™ NPM1 (MutA, B, C&D) mutacijų aptikimas. rinkinys	16 02 01 90
B-TRMF000028405FIP1RT247C	FIP1-RT24	geneMAP™™ FIP1L1-PDGFRα aptikimo rinkinys	16 02 01 90
B-TRMF000028405WT1RT24NL	WT1-RT24	geneMAP™™ WT1 ekspresijos analizės rinkinys	16 02 01 90
B-TRMF000028405MPLRT25QN	MPL-RT25	geneMAP™™ MPL W515 A/L/K/R mutacijų aptikimo rinkinys	16 02 01 90

Parašas: Stambulas, Turkija 2022-04-08

Mehmet Ekti (vadovas)

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Pagrindinis UDI-DI	Katalogo numeris	produkto pavadinimas	EDMA kodas
B-TRMF000028405FLT3RT25BB	FLT3-RT25	geneMAP™™ FLT3 D835Y mutacijų aptikimo rinkinys	16 02 01 90
B-TRMF000028405FLT3FA255Q	FLT3-FA25	geneMAP™™ FLT3 ITD/D835Y mutacijų aptikimas, rinkinys	16 02 01 90
B-TRMF000028405cKITRT25XK	CKIT-RT25	geneMAP™™ C-KIT D816V mutacijų aptikimo rinkinys	16 02 01 90
B-TRMF000028405JK12QRT5ZG	JK12Q-RT50	geneMAP™™ JAK2 Exon12 mutacijų aptikimo rinkinys	16 02 01 90
B-TRMF000028405MGMRT50MB	MGM-RT50	geneMAP™™ MGMT metilinimo analizės rinkinys	16 02 01 90
B-TRMF000028405MLH1RT509V	MLH1-RT50	geneMAP™™ MLH1 metilinimo analizės rinkinys	16 02 01 90
B-TRMF000028405PDLRT24MB	PDL-RT24	geneMAP™™ PD-L1 ekspresijos analizės rinkinys	16 02 01 90
B-TRMF000028405HERRT24KJ	HER-RT24	geneMAP™™ HER-2 ekspresijos analizės rinkinys	16 02 01 13
B-TRMF000028405NTRKRT24TC	NTRK-RT24	geneMAP™™ NTRK sintezės transkripto aptikimo rinkinys	16 02 01 90
B-TRMF000028405MTBRT100HC	MTB-RT100	geneMAP™™ MTB aptikimo rinkinys	15 01 07 40
B-TRMF000028405MTBNRT10LX	MTBN-RT100	geneMAP™™ MTB/NTM aptikimo rinkinys	15 01 07 40
B-TRMF000028405MTBMDRRTNE	MTB/MDR-RT50	geneMAP™™ MTB/MDR aptikimo rinkinys	15 01 07 40
B-TRMF000028405MTBXDRRTS7	MTB/XDR-RT25	geneMAP™™ MTB/XDR aptikimo rinkinys	15 01 07 40
B-TRMF000028405BORRT50LF	BOR-RT50	geneMAP™™ borelijų aptikimo rinkinys	15 01 06 90
B-TRMF000028405nCoVRT50FZ	nCoV-RT500	geneMAP™™ 2019-nCoV (SARS-CoV-2) aptikimo rinkinys	15 04 09 40
B-TRMF000028405nCoVTRT50K9	nCoV-RT500	geneMAP™™ 2019-nCoV Triple Detection Kit	15 04 09 40
B-TRMF000028405RV2RT100FA	RV2-RT100	geneMAP™™ Respiratory Viral Panel 2 (2019-nCoV, Inf A/B, RSV A/B)	15 30 02 42
B-TRMF000028405RV3RT100FP	RV3-RT100	geneMAP™™ Respiratory Viral Panel 3 (2019-nCoV, Inf A/B)	15 30 02 42
B-TRMF000028405DPYDRT25KS	DPYD-RT25	geneMAP™™ DPYD mutacijų aptikimo rinkinys	16 02 01 90
B-TRMF000028405MPRT50SP	MP-RT50	geneMAP™™ beždžionių raupų PGR aptikimo rinkinys	15 04 09 40
B-TRMF000028405HPVGR50MX	HPVG-RT50	geneMAP™™ HPV HR ir 6/11 genotipų rinkinys	15 04 08 41
B-TRMF000028405RVMRT50W3	RM-RT50	geneMAP™™ kvėpavimo sistemos pagrindinis skydelis	15 30 04 42

Parašas: Stambulas, Turkija 2022-04-08
Mehmet Ekti (vadovas)

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*Beleymas teikiama.
Suivina, St. balayimene*

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