

		DECLARATION OF CONFORMITY		Document No:		UB.05.HE	
				Release Date:		09.02.2026	
				Revision Date:		-	
				Revision No		00	
The manufacturer, Ear-Teknik A.Ş., located at 59930 Ergene / Tekirdağ, hereby declares under its sole responsibility that the HELIX brand Behind-The-Ear (BTE) hearing devices, including related hearing aid accessories where applicable, listed below are classified as Class IIa medical devices and are designed and manufactured in compliance with the requirements of Council Directive 93/42/EEC (MDD).							
The devices listed below are in conformity with the essential requirements and other applicable provisions of the following:							
Basic UDI-DI			08682549138TE16Q				
EU directives			Council Directive 93/42/EEC				
Conformity assessment procedure			Annex II of 93/42/EEC				
Certificate registration no			1984 - MDD - 20- 685				
Classification of Device			Class IIa, Rule 9 (according to Annex IX of Council Directive 93/42/EEC)				
Applied standards and specifications used for conformity assessment (standard versions valid on the date of issue of this document)			TS EN ISO 13485: 2016				
			TS EN ISO 14155: 2020				
			TS EN ISO 14971: 2020				
			TS EN ISO 15223-1: 2021				
			TS EN ISO 20417: 2021				
			TS EN 60601-1: 2007 / A1: 2014				
			TS EN 60601-2-66: 2020				
			IEC 60118-13: 2020				
			TS EN ISO 60118-7: 2009				
			TS EN ISO 60118-0: 2024				
			TS EN 62366-1: 2015				
			TS EN ISO 10993-5: 2010				
			TS EN ISO 10993-10: 2023				
TS EN ISO 10993-12: 2021							
TS EN ISO 62304: 2009 / A1: 2016							
Model	Variant	Catalog Number	Product Name / Type	EMDN Code	GMDN Code	Category	
ALFA W	Alfa W 100 RIE-M	137-024501119	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 100 RIE-MR	137-024501120	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 100 S-P	137-024501121	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 100 SPn	137-02450173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 200 RIE-M	138-024601119	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 200 RIE-MR	138-024601120	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 200 S-P	138-024601121	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 200 SPn	138-02460173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 300 RIE-M	139-024701119	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 300 RIE-MR	139-024701120	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 300 S-P	139-024701121	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 300 SPn	139-02470173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 400 RIE-M	140-024801119	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 400 RIE-MR	140-024801120	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 400 S-P	140-024801121	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Alfa W 400 SPn	140-02480173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 110 RIE-M	147-024101119	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 110 RIE-MR	147-024101120	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 110 S-P	147-024101121	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 110 SPn	147-02410173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 220 RIE-M	148-024201119	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 220 RIE-MR	148-024201120	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 220 S-P	148-024201121	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 220 SPn	148-02420173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 330 RIE-M	149-024301119	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 330 RIE-MR	149-024301120	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 330 S-P	149-024301121	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 330 SPn	149-02430173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 440 RIE-M	150-0214401119	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 440 RIE-MR	150-024401120	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 440 S-P	150-024401121	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Fast 440 SPn	150-02440173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
TINNITUS	AlJ, F- TRT	131-02300170	Behind The Ear Tinnitus Masker	Y21450601	43018	Hearing Aid	
	AlJ, R- TRT	131-02300136	Behind The Ear Tinnitus Masker	Y21450601	43018	Hearing Aid	
FORCE	Force 100 RIE	133-02330136	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Force 100 FO	133-02330170	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Force 100 SP	133-02330173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Force 100 HP	133-02330180	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Force 200 RIE	134-02340136	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Force 200 FO	134-02340170	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Force 200 SP	134-02340173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Force 200 HP	134-02340180	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Force 300 RIE	142-02350136	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	
	Force 300 FO	142-02350170	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid	

	Force 300 SP	142-02350173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Force 300 HP	142-02350180	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Force 400 RIE	141-02360136	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Force 400 FO	141-02360170	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Force 400 SP	141-02360173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Force 400 HP	141-02360180	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
CLEVER	Clever 110 RIE	143-02370136	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 110 FO	143-02370170	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 110 SP	143-02370173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 110 HP	143-02370180	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 220 RIE	144-02380136	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 220 SO	144-02380170	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 220 SP	144-02380173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 220 HP	144-02380180	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 330 RIE	145-02390136	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 330 SO	145-02390170	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 330 SP	145-02390173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 330 HP	145-02390180	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 440 RIE	146-02400136	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 440 SO	146-02400170	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 440 SP	146-02400173	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	Clever 440 HP	146-02400180	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
FREE	FR M	105-02100119	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	FR MP	105-02100178	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	FR M4	105-02100121	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	FR M4P	105-02100179	Behind The Ear Hearing Aids, Digital Programmable	Y21450601	34671	Hearing Aid
	FR MT	105-02100141	Behind The Ear Hearing Aids	Y21450601	34671	Hearing Aid
	FR LT	105-02100144	Behind The Ear Hearing Aids	Y21450601	34671	Hearing Aid

Notified Body	Kiwa Belgelendirme Hizmetleri A.Ş. Kiwa Turkey
Notified Body Identification Number	ITOSB 9. Cadde No 15 Tepeören Tuzla - İstanbul - Turkey
Date of certification	CE 1984
Valid until	06.08.2020
SRN	27.05.2024
Technical File is held by	TR-MF-000034630
Place and Date of Issue	EAR TEKNİK İŞİTME VE ODIOMETRİ CİHAZLARI SAN. VE TİC. A.Ş. Karamehmet Mahallesi Adnan Arısoy Bulvarı Avrupa Serbest Bölgesi No: 11 İç Kapı No: 202 59930 Ergene-Tekirdağ / TÜRKİYE info@eartechnic.com www.eartechnic.com
Quality Management Representative Damla ŞAN	ERGENE - TEKİRDAĞ 09.02.2026 

		DECLARATION OF CONFORMITY		Document Code		UB.06.HE	
				Release Date		09.02.2026	
				Revision Date		-	
				Revision No		00	
The manufacturer, Ear-Teknik A.Ş., located at 59930 Ergene / Tekirdağ, hereby declares under its sole responsibility that the EARNET brand In-The-Ear (ITE) Faceplate Kits hearing devices, including related hearing aid accessories where applicable, listed below are classified as Class IIa medical devices and are designed and manufactured in compliance with the requirements of Council Directive 93/42/EEC (MDD).							
The devices listed below are in conformity with the essential requirements and other applicable provisions of the following:							
Basic UDI-DI			0868254913ITE288				
EU directives			Council Directive 93/42/EEC				
Conformity assessment procedure			Annex II of 93/42/EEC				
Certificate registration no			1984 - MDD - 20- 685				
Classification of Device			Class IIa, Rule 9 (according to Annex IX of Council Directive 93/42/EEC)				
Applied standards and specifications used for conformity assessment (standard versions valid on the date of issue of this document)			TS EN ISO 13485: 2016				
			TS EN ISO 14155: 2020				
			TS EN ISO 14971: 2020				
			TS EN ISO 15223-1: 2021				
			TS EN ISO 20417: 2021				
			TS EN 60601-1: 2007 / A1: 2014				
			TS EN 60601-2-66: 2020				
			IEC 60118-13: 2020				
			TS EN ISO 60118-7: 2009				
			TS EN ISO 60118-0: 2024				
			TS EN 62366-1: 2015				
			TS EN ISO 10993-5: 2010				
			TS EN ISO 10993-10: 2023				
TS EN ISO 10993-12: 2021							
TS EN ISO 62304: 2009 / A1: 2016							
Model	Variant	Catalog Number	Product Name / Type	EMDN Code	GMDN Code	Category	
ALFA W	Alfa W 100 MicP	137-02450192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Alfa W 100 ITE-P	137-02450163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Alfa W 200 MicP	138-02460192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Alfa W 200 ITE-P	138-02460163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Alfa W 300 MicP	139-02470192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Alfa W 300 ITE-P	139-02470163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Alfa W 400 MicP	140-02480192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Alfa W 400 ITE-P	140-02480163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
FAST	Fast 110 MicP	147-02410192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Fast 110 ITE-P	147-02410163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Fast 220 MicP	148-02420192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Fast 220 ITE-P	148-02420163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Fast 330 MicP	149-02430192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Fast 330 ITE-P	149-02430163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Fast 440 MicP	150-02440192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Fast 440 ITE-P	150-02440163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
FORCE	Force 100 IIC	133-02330186	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 100 CIC	133-02330101	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 100 CIC-P	133-02330192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 100 ITH-D	133-02330164	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 100 ITH-P	133-02330163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 200 IIC	134-02340186	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 200 CIC	134-02340101	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 200 CIC-P	134-02340192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 200 ITH-D	134-02340164	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 200 ITH-P	134-02340163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 300 IIC	142-02350186	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 300 CIC	142-02350101	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 300 CIC-P	142-02350192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 300 ITH-D	142-02350164	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 300 ITH-P	142-02350163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 400 IIC	141-02360186	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 400 CIC	141-02360101	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 400 CIC-P	141-02360192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 400 ITH-D	141-02360164	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Force 400 ITH-P	141-02360163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
Clever	Clever 330 IIC	145-02390186	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Clever 330 CIC	145-02390101	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Clever 330 CIC-P	145-02390192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Clever 330 ITH-D	145-02390164	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Clever 330 ITH-P	145-02390163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Clever 220 IIC	144-02380186	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	
	Clever 220 CIC	144-02380101	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid	

CLEVER	Clever 220 CIC-P	144-02380192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 220 ITH-D	144-02380164	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 220 ITH-P	144-02380163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 110 IIC	143-02370186	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 110 CIC	143-02370101	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 110 CIC-P	143-02370192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 110 ITH-D	143-02370164	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 110 ITH-P	143-02370163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 440 IIC	146-02400186	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 440 CIC	146-02400101	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 440 CIC-P	146-02400192	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 440 ITH-D	146-02400164	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 440 ITH-P	146-02400163	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
FREE	FR ITC	105-02100107	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
	FR ITH	105-02100111	In The Ear Hearing Aids faceplate kits, Digital Programmable	Y21450602	34672	Hearing Aid
	FR ITC-T	105-02100138	In The Ear Hearing Aids faceplate kits	Y21450602	34672	Hearing Aid
	FR ITH-T	105-02100140	In The Ear Hearing Aids faceplate kits	Y21450602	34672	Hearing Aid
Notified Body		Kiwa Belgelendirme Hizmetleri A.Ş. Kiwa Turkey				
Notified Body Identification Number		ITOSB 9. Caddesi No 15 Tepeören Tuzla - İstanbul - Turkey				
Date of certification		CE 1984				
Valid until		06.08.2020				
SRN		27.05.2024				
Technical File is held by		TR-MF-000034630				
Place and Date of Issue		EAR TEKNİK İŞİTME VE ODİOMETRİ CİHAZLARI SAN. VE TİC. A.Ş. Karamahmet Mahallesi Adnan Arısoy Bulvarı Avrupa Serbest Bölgesi No: 11 İç Kapı No: 202 59930 Ergene-Tekirdağ / TÜRKİYE info@eartechnic.com www.eartechnic.com				
Quality Management Representative Damla ŞAN		ERGENE - TEKİRDAĞ 09.02.2026				
						



DECLARATION OF CONFORMITY

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09.02.2026

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Revision No

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The manufacturer, Ear-Teknik A.Ş., located at 59930 Ergene / Tekirdağ, hereby declares under its sole responsibility that the EARNET brand In-The-Ear (ITE) hearing devices, including related hearing aid accessories where applicable, listed below are classified as Class IIa medical devices and are designed and manufactured in compliance with the requirements of Council Directive 93/42/EEC (MDD).

The devices listed below are in conformity with the essential requirements and other applicable provisions of the following:

Basic UDI-DI

0868254913ITE189

EU directives

Council Directive 93/42/EEC

Conformity assessment procedure

Annex II of 93/42/EEC

Certificate registration no

1984 - MDD - 20- 685

Classification of Device

Class IIa, Rule 9 (according to Annex IX of Council Directive 93/42/EEC)

Applied standards and specifications used for conformity assessment (standard versions valid on the date of issue of this document)

TS EN ISO 13485: 2016

TS EN ISO 14155: 2020

TS EN ISO 14971: 2020

TS EN ISO 15223-1: 2021

TS EN ISO 20417: 2021

TS EN 60601-1: 2007 / A1: 2014

TS EN 60601-2-66: 2020

IEC 60118-13: 2020

TS EN ISO 60118-7: 2009

TS EN ISO 60118-0: 2024

TS EN 62366-1: 2015

TS EN ISO 10993-5: 2010

TS EN ISO 10993-10: 2023

TS EN ISO 10993-12: 2021

TS EN ISO 62304: 2009 / A1: 2016

Model	Variant	Catalog Number	Product Name / Type	EMDN Code	GMDN Code	Category
TINNITUS	AI_Box-S TRT	131-023001113	In The Ear Tinnitus Masker	Y21450602	43826	Hearing Aid
	AI_Box TRT	131-02300171	In The Ear Tinnitus Masker	Y21450602	43826	Hearing Aid
FORCE	Force 100 Box	133-02330171	In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Force 200 Box	134-02340171	In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Force 300 Box	142-02350171	In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Force 400 Box	141-02360171	In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
CLEVER	Clever 110 Box	143-02370171	In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 220 Box	144-02380171	In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 330 Box	145-02390171	In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Clever 440 Box	146-02400171	In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid

Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş. Kiwa Turkey
ITOSB 9. Cadde No 15 Tepeören Tuzla - İstanbul - Turkey

Notified Body Identification Number

CE 1984

Date of certification

06.08.2020

Valid until

27.05.2024

SRN

TR-MF-000034630

Technical File is held by

EAR TEKNİK İŞİTME VE ODIOMETRİ CİHAZLARI SAN. VE TİC. A.Ş.
Karamelhet Mahallesi Adnan Arısoy Bulvarı
Avrupa Serbest Bölgesi No: 11 İç Kapı No: 202
59930 Ergene-Tekirdağ / TÜRKİYE
info@eartechnic.com
www.eartechnic.com

Place and Date of Issue

ERGENE - TEKIRDAG 09.02.2026

Quality Management Representative

Damla ŞAN



		DECLARATION OF CONFORMITY		Document Code	UB.08.HE	
				Release Date	09.02.2026	
				Revision Date	-	
				Revision No	00	
The manufacturer, Ear-Teknik A.Ş., located at 59930 Ergene / Tekirdağ, hereby declares under its sole responsibility that the EARNET brand Transducer In The Ear (TIE) hearing devices, including related hearing aid accessories where applicable, listed below are classified as Class IIa medical devices and are designed and manufactured in compliance with the requirements of Council Directive 93/42/EEC (MDD).						
The devices listed below are in conformity with the essential requirements and other applicable provisions of the following:						
Basic UDI-DI		0868254913TIE18X				
EU directives		Council Directive 93/42/EEC				
Conformity assessment procedure		Annex II of 93/42/EEC				
Certificate registration no		1984 - MDD - 20- 685				
Classification of Device		Class IIa, Rule 9 (according to Annex IX of Council Directive 93/42/EEC)				
Applied standards and specifications used for conformity assessment (standard versions valid on the date of issue of this document)		TS EN ISO 13485: 2016				
		TS EN ISO 14155: 2020				
		TS EN ISO 14971: 2020				
		TS EN ISO 15223-1: 2021				
		TS EN ISO 20417: 2021				
		TS EN 60601-1: 2007 / A1: 2014				
		TS EN 60601-2-66: 2020				
		IEC 60118-13: 2020				
		TS EN ISO 60118-7: 2009				
		TS EN ISO 60118-0: 2024				
		TS EN 62366-1: 2015				
		TS EN ISO 10993-5: 2010				
		TS EN ISO 10993-10: 2023				
		TS EN ISO 10993-12: 2021				
		TS EN ISO 62304: 2009 / A1: 2016				
Model	Variant	Catalog Number	Product Name / Type	EMDN Code	GMDN Code	Category
TIE	Tie 100	128-02290188	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie 200	128-02290189	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie 300	128-02290190	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie 400	128-02290191	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie X 100	132-02310188	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie X 200	132-02310189	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie X 300	132-02310190	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie X 400	132-02310191	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie 110	128-022901106	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie 220	128-022901107	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie 330	128-022901108	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie 440	128-022901109	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie X 110	132-023101106	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie X 220	132-023101107	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie X 330	132-023101108	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
	Tie X 440	132-023101109	Transducer In The Ear Hearing Aids, Digital Programmable	Y21450602	34672	Hearing Aid
Notified Body		Kiwa Belgelendirme Hizmetleri A.Ş. Kiwa Turkey ITOSB 9. Caddesi No 15 Tepeören Tuzla - İstanbul - Turkey				
Notified Body Identification Number		CE 1984				
Date of certification		06.08.2020				
Valid until		27.05.2024				
SRN		TR-MF-000034630				
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