ENEU Medical Device Regulation 2017/745
Declaration Of Conformity

SRN : TR-MF-000046503

AURAFIX HEALTH PRODUCTS FORE

Manufacturer Name	**AURAFIX HEALTH PRODUCTS DIŞ TİCARET VE SANAYİ ANONİM ŞİRKETİ**		
Manufacturer Adress	Adil Mah. Ekol Cad. No:12A SULTANBEYLİ İSTANBUL		
Manufacturer Individual Identity No.			
Classification	EU 2017/745- Medical Device Regulation / Annex VIII Rule I, Class -I Other Non-Steril		
Product Name and Descriptive Informations and Descriptions	Presented in the attached list.		
Confirmty Assessment Procedure	■	ANNEX-IV (EK II & III)	Declaration Of Conformity
(Annexes executed in the product evaluation are marked)	☐	ANNEX-IX (PART I & III)	Quality Management System
	☐	ANNEX-IX (PART II)	Technical Documentation Mod.
	☐	ANNEX-X	Type Examination
	☐	ANNEX-XI (PART A)	Production Quality Assurance
	☐	ANNEX-XI (PART B)	Product Verification
Verification Certificates	-		
Other EU Legislation/ Common Specifications / Harmonized Standarts To Which The Product Complies	EN ISO 13485:2016 , EN ISO 9001:2015 ,EN ISO 15223-1:2016 , EN ISO 14971, TSE EN ISO 16495:2014 EN ISO 22523:2006-		

IGN TRADE AND INDUSTRY INC. As a company, we declare under our sole responsibility that the devices covered by this declaration comply with the **EU 2017/745 Medical Device Regulation** of the European Parliament and of the Council on Medical Devices and that the requirements specified in the Regulation are fulfilled for these devices.

Signature Date And Place : 10.01.2025 | İSTANBUL

Signed By : Türkay GÜLHAN

Mission : Company Owner

Board [Sign And Stamp]

AURAFIX HEALTH
PRODUCTS DIS TIC. VE SAN. A.Ş.
ADİL MH. EKOL CD. NO:12/A
SULTANBEYLİ/İSTANBUL
SULTANBEYLİ V.D. : 859 113 2300