APOSTILLE

(Convention de La Haye du 5 Octobre 1961)

1. Ülke/Country/Pays/Staat TÜRKİYE - LA TURQUIE

İşbu resmi belge/This public document/Le présent acte public/Dieses zeugnis wurde

2. Rahmi Sertaç KARATEPE tarafından imzalanmıştır./Has been signed by/a été signé par/durch ... unterschrieben

3. İmzalayanın sıfatı Yetkili'dır./Acting in the capacity of/Agissant en qualité de/Titel des Unterzeichneten

4. İstanbul Ticaret Odası 'nin mühür/damgasını taşımaktadır-bears the seal/stamp of-/est revétu du sceau/timbre de-trägt Siegel/Stempel von

TASDİK / CERTIFIED / ATTESTE / BEGLAUBIGUNG:

5. Sultanbeyli Kaymakamlığı' da/at/à/in

6. 23.06.2023 günü/the/le/Am

7. V.H.K.İ Levent SARIKAYA tarafından/by/par/durch den/die

8. No : 16101 ile tasdik edilmiştir./No:/sous No:/unter Nr.

9. Mühür - Damga/Seal-stamp/Sceau-timbre/Siegel-Stempel

.....

10. İmza/Signature/Signature/Unterschrift:

.....

ENEU Medical Device Regulation 2017/745
Declaration Of Conformity

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-		

AURAFIX HEALTH PRODUCTS FOREIGN 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 : 02.01.2023 | İSTANBUL

Signed By : Türkay GÜLHAN

Mission : Company Owner

Board [Sign And Stamp]

AURAFIX HEALTH PRODUCTS DIŞ TİC. VE SAN. A.Ş. ADİL MH. EKOL CD. NO:12-A SULTANBEYLİ İSTANBUL SULTANBEYLİ V.D. : 859 113 2300

ISTANBUL
CHAMBER OF COMMERCE
Membership Services Department

23/06/2023

AURAFİX HEALTH PRODUCTS DIŞ
TİCARET VE SANAYİ ANONİM ŞİRKETİ

COMPANY HAS BEEN REGISTERED TO OUR
CHAMBER UNDER THE REGISTRATION
NUMBER 486654

PRESENT APPROVAL DOES NOT COVER THE CONTENT OF THE DOCUMENT.

for the SECRETARY GENERAL
OF THE ISTANBUL CHAMBER OF COMMERCE
RAHMİ SERTAÇ KARATEPE