Manufacturer:	*European* Representative:	*Document id. and Rev. Number:*
AYSET TIBBI URUNLER VE PLASTIK TEKSTIL ELEKTRONiK GIDA TEMiZLiK MADDELERI SAN. A.. Sarihamzali Koyu Yolu Uzeri No:54 Seyhan Adana, Turkey	Caihan International Marketing whose registered office is at Kotterner Str. 46 D8-7435 Kempten, GERMANY	D15-06

European Declaration of Conformity to the In Vitro Diagnostic Medical Devices, 98/79/EC

CE

Product Name	**VACUUM TUBE**
Product Model Number(s)	**with Clot Activator and Gel Separator x 5 ml of blood, sterile**
Lot Number	12985-6 / Expire date: 2017.11
Description	Blood tube is a device to collect blood samples from the body for eventual laboratory testing.
Sterile	Yes
Classification / Rule	Others, According to the Appendix VII
Conformity Assessment Route	Annex II of IVD *98/791EC*
Applicable Standards	EN 980:2003 EN ISO 14971, EN 591:2001 EN ISO 13485:2003

Declaration

AYSET TIBBI URUNLER VE PLASTIK TEKSTIL ELEKTRONIK GIDA TEMIZLIK MADDELERI SAN. A.S. declares that the above product to which this declaration relates, bears the CE Marking, and is in conformity with the applicable requirements of the Directive 98179/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, which allows its free distribution, sale and circulation in EEC.

All supporting documentation is retained at the manufacturer's premises

The present EC Declaration of Conformity is applicable to all mentioned in vitro diagnostic medical devices, manufactured by AYSET TIB URUNLER VE PLASTIK TEKSTIL ELEKTRONIK GIDA TEMIZLIK MADDELERI SAN. A.S. Adana, Turkey, and/or anyway realized under the Manufacturer's Certified Quality System control for a period of about 1 year from the approval date of the present document.

Start date of CE Mark : **21.01.2015**

Signature on behalf of

AYSET TIBBI URUNLER VE PLASTIK TEKSTIL ELEKTRONIK GIDA TEMIZLIK MADDELERI SAN.AS.

Date :01.10.2015

Signature

HASAN AYTEKIN

AYSET *General MANAGER*

Digitally signed by Granaci Boris
Date: 2019.03.29 14:18:40 EET
Reason: MoldSign Signature
Location: Moldova