

Manufacturer:

AYSET TIBBI URUNLER VE PLASTIK TEKSTIL
ELEKTRONIK GIDA TEMIZLIK MADDELERI SAN. A..
Sarihamzali Koyu Yolu Uzeri No:54 Seyhan
Adana, Turkey

European Representative:

Caihan International Marketing whose
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Document id. and Rev. Number:

D15-06

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



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|------------------------------------|--|
| Product Name | Vacuum Tube |
| Product Model Number(s) | with Sodium Citrate (3, 8%) for 1,5 ml of blood |
| Lot Number | 5674-3 / Expire date: 2019.11 |
| 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 98/79/EC |
| 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 98/79/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 TIBBI 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 : 21.01.2014

Signature on behalf of

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

Date : 21.10.2014

Signature

HASAN AYTEKIN

AYSET General MANAGER

