



bilimsel
TIBBİ ÜRÜNLER



DECLARATION OF CONFORMITY

MANUFACTURER:

Name : BİLİMSEL TIBBİ ÜRÜNLER PAZARLAMA SAN.VE TİC.LTD. ŞTİ.
Address: Dokuz Eylül Mah. 312/1 sok. No: 12 Gaziemir- İzmir -TURKEY

DECLARED PRODUCT INFO:

Product Trademark:

bt
products

Product Name:

bt- sedi 20

AUTO ESR ANALYZER

REALATED STANDARTS:

TS EN ISO 13485: 2003	"Medical devices - Quality management systems - Requirements for regulatory purposes"
TS EN ISO 9001: 2008	"Quality Management Systems-Requirements"
EN 61326-2-6: 2006	"Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In-vitro diagnostic (IVD) medical equipment."
TS EN 980: 2008	"Symbols for use in the labelling of medical devices"
TS EN 591: 2002	"In vitro diagnostic systems - Requirements for user manuals for in vitro diagnostic instruments for professional use"
TS EN 14971: 2007	"Medical devices - Application of risk management to medical devices"
TS EN 61010-2-101: 2005	"Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment"

We hereby declare that the above mentioned product
is manufactured in conformity with the related applicable provisions of the EU Conseil Directive
98/79/EC and Turkish Health Ministry's Regulation "In Vitro Diagnostic Medical Devices Directive"
Annex III (IVD,other) published in official journal no 26398 on January 9th, 2007.

Declaration issued and signed on February 20th, 2018.

Ömer Biçer,
General Manager

Rev.tar./No: 20.02.2018/1

BİLİMSEL TIBBİ ÜRÜNLER PAZARLAMA SANAYİ VE TİCARET LİMİTED ŞİRKETİ

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