

## DECLARATION OF CONFORMITY

**MANUFACTURER: DORT-A TIP MALZEMELERİ SANAYİ İTHALAT İHRACAT TİCARET LİMİTED ŞİRKETİ**

Address: Balıkhisar Mahallesi Köyüçü Serpmeleri No795A Akyurt Ankara Turkey

Products: Bowie-Dick Test Packages, Indicator Strips ( H2O2 Indicator Strip, Formaldehyde Indicator Strip, Ethylene Oxide Indicator Strip, Dry heat Indicator Strip, Type 4 Indicator Strip, Type 5 Indicator Strip, Type 6 Indicator Strip ), Type 5 Integrator, Registration Card, Longtime Steam Biological Indicator, Longtime Ethylene Oxide Biological Indicator, Longtime H2O2 ( Plasma ) Biological Indicator, Helix Group Tests, PCD Group Tests, Ethylene Oxide load control test, Autoclave Tapes ( Steam, Ethylene Oxide, Plasma, Formaldehyde ), Container Label, Container Seal, Container Filter, Documentation Labels with Indicator, Reel Barcode Labels with Indicator; Label Gun ,, Washer Disinfectors Ultrasonic Devices and Washing Control Tests of Surgical Instruments ( Pro Test, Hemo Tests, Washer Test, Cannulacontrol Test, Soniccontrol Test ).

Above described products complied with below norms.

DOCUMENT NO	TITLE	EDITION / DATE OF ISSUE
TS EN ISO 11140-1	Chemical Indicators	18.02.2015
TS EN ISO 11140-4	Bowie Dick Test Pack	31.01.2008
TS EN 11138-1	Biological Indicators	29.04.2008
TS EN 15883-1	Washing Machine Disinfectant Residue Test	30.10.2014

Additional information:

The development, production and the distribution is supported with a Quality Management System according to the requirements of the ISO 9001:2015 and ISO 13485:2016. The Quality Management System is certificated through the notified body ROYALCERT (Certificate No: 108 / DOR09B and 108 / DOR13A). As proof of the conformity of the products with the requirements of the Council Directive 93/42/EEC concerning Medical devices were considered in class 1 non sterilised and non measuring products.

Declaration of Conformity is valid for 1 year.

Ankara Turkey

27.12.2021

Canan Öktem

General Manager