

**DECLARATION OF CONFORMITY**

In accordance with ISO / IEC

No 01 / 2015

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

Address: Balıkhisar Mahallesi Köyiçi Serpmeleri No795A Akyurt Ankara Turkey

Products: Sterilization Reels and Pouches (Flat,Gusset,Tyvek), Self Adhesive Sterilization Pouches, Bowie-Dick Test Packages, Indicator Strips ( H2O2 Indicator Strip, Formaldehyde Indicator Strip, Ethylene Oxide Indicator Strip, Dry heat Indicator Strip, Class 4 Indicator Strip, Class 5 Indicator Strip, Class 6 Indicator Strip ), Class 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 ), Wrap and Crepe Paper Sheets, Sterile Container System, 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, Sonicontrol Test ) ), Double Biological Indicator Test Package ( Biological Indicator- Class 5 Integrator ), Biological Test Package,Double Load Control Test Package ( Class 5 Integrator and Inner PCD Class 6 Indicator ), Triple Biological Indicator Test Package ( Biological Indicator, Class 5 Integrator and Inner PCD Class 6 Indicator )

Above described products complied with below norms.

| DOCUMENT NO       | TITLE                                                            | EDITION / DATE OF ISSUE |
|-------------------|------------------------------------------------------------------|-------------------------|
| 93/42/EEC         | Council Directive 93 / 42 / EEC<br>Concerning Medical Directives | 07.06.2011              |
| TS EN 868-5       | Material Packaging                                               | 27.12.2012              |
| TS EN ISO 11140-1 | Chemical Indicators                                              | 18.02.2015              |
| TSE EN 868-9      | Material Packaging                                               | 19.01.2010              |
| 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 suported with a Quality Management System according to the requirements of the ISO 9001:2015 and ISO 13485:2012. 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 products.

Decleration of Conformity is valid for 1 year.

Ankara Turkey

12.02.2019

Canan Öktem

General Manager