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Dört-A Tıp Malzemeleri
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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 Pack 4ABD, Indicator Strips (H2O2 Indicator Strip, Formaldehyde Indicator Strip, Ethylene Oxide Indicator Strip, Dry heat Indicator Strip, Class 4 Indicator Card 4ASI, Class 5 Indicator Strip, Class 6 Indicator Strip, Class 6 Steam Indicator 3,5 minutes 4A6SI), 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, 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, Cannula control 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 Concerning Medical Devices	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 Disinfector 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 sterilized products.

Declaration of Conformity is valid for 1 year.

Ankara Turkey 20.01.2021

Canan Öktem

General Manager

Digitally signed by Cojocaru Vera
Date: 2021.11.26 09:13:14 EET
Reason: MoldSign Signature
Location: Moldova