

DECLARATION OF CONFORMITY

MANUFACTURER: DORT-A TIP MALZEMELERI SANAYI İTHALAT İHRACAT TİCARET LİMİTED ŞİRKETİ

Address: Balıkhisar Mahallesi Köyiçi 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, Lontgtime 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, Sonicontrol 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 Disinfector 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 13485:2016. 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.

Decleration of Conformity is valid for 1 year.

Ankara Turkey

Canan Öktem

General Manager

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VERIFICATION OF CONFORMIT

S/N: 001404

Applicant

manufacturer:

Name and address of

Name and address of

Product name and types:

No.: ICR Polska/VC/MH210103/A1 replaces ICR Polska/VC/MH210103

DÖRT-ATIP MALZEMELERİ SANAYİ İTHALAT İHRACAT TİCARET LİMİTED ŞİRKETİ BALIKHİSAR MH. KÖYİCİ SERPMELERİ NO:795/A AKYURT / ANKARA / TURKEY

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• BANTLAR / TAPES:

- BUHAR (CLASS I) / STEAM (CLASS I),
- ETİLEN ÖKSİT (CLASS I) / ETHYLENÊ OXIDE (CLASS I),
- FORMALDEHİT (CLASS I) / FORMALDEHYDE (CLASS I),
- HİDROJEN PEROKSİT (CLASS I) / HYDROGEN PEROXIDE (CLASS I)
- **INDIKATOR KART STRIPLER / INDICATOR CARD STRIPS:**
- BUHAR (3,5-7 DK (CLASS 6) / STEAM (3,5-7 MIN. (CLASS 6),
- BUHAR (CLASS 4, CLASS 5) / STEAM (CLASS4, CLASS 5),
- ETILEN OKSIT (CLASS 5) / ETHYLENE OXIDE (CLASS 5),
- HIDROJEN PEROKSIT(CLASS 4) / HYDROGEN PEROXIDE (CLASS 4),
- FORMALDEHIT(CLASS4) / FORMALDEHYDE (CLASS 4),
- KURU ISI (CLASS 1-2) / DRY HEAT (CLASS 1-2)
- YÜK TESTLERİ / LOAD TESTS:
- (KÜME TESTLERİ / GROUP TESTS),
- PCD (CLASS 6) / HELIX (CLASS 6)
- ETİKETLER / LABELS:
 - BUHAR (CLASS 1) / STEAM (CLASS 1),
 - ETILEN OKSIT (CLASS 1) / ETHYLENE OXIDE (CLASS 1),
 - FORMALDEHIT (CLASS 1) / FORMALDEHYDE (CLASS 1),
 - HIDROJEN PEROKSIT (CLASS 1) / HYDROGEN PEROXIDE (CLASS 1)

Product trademark:

4a med(c producing health for the world

This document confirms that the product sample meets the requirements of the following standards:

EN ISO 11140-1:2009

The assessment process has been carried out in accordance with individual rules and conditions agreed with the applicant. Evaluation has been carried out in accordance with:

Test reports: Tests conducted by:	partial report file Saniter Gıda – Çevre Bilimi Gözetim Ve Mühendislik Hiz. Tur. Tic. A.Ş.
Issue date:	13.10.2021
Initial issue date:	09.02.2021
Expiration date:	08.02.2026

Remarks:

Document refers to the above mentioned product and its conformity in regards of above mentioned standard(s) was proven on test sample

Document was issued on voluntary basis and does not imply meeting all essential requirements, assessment of the seriesproduction or any other restricted Notified Bodies conformity assessment procedure appropriate for the product Document status can be checked: https://cert.icrpolska.com/

CE marking remarks:

CE mark is not sanctioned by the following document

CE mark given here as reference, can be only use by the manufacturer after applying all essential requirements from relevant directives



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Director: Rafał Kalinowski Warsaw, 13.10.2021