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producing health for the world
Dört-A Tıp Malzemeleri Sanayi İth. İhr. Tic. Ltd. Şti.
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DECLARATION OF CONFORMITY

MANUFACTURER: DORT-A TIP MALZEMELERİ SANAYİ 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 27.12.2021

Canan Öktem

General Manager

DENTSTORE SRL
Reg: J40/15190/2017
CUI: RO 29777715
Unicredit Tiriac Bank-Rosetti
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FISA TEHNICA si INSTRUCTIUNI UTILIZARE INDICATOR ABUR CLASA 5 – INTEGRATOR

Descrierea produsului
Test integrator laminat pentru sterilizare la autoclav 134°C -7 min/ 121°C-20 min. Monitorizeaza toti parametrii critici: timp, temperatura, absenta aerului si calitatea aburului. Monitorizeaza toate ciclurile de sterilizare cu abur (121°C-134°C) si toti parametrii ciclului. Produsul detecteaza eventualele deficiente in functionarea echipamentului sau greseli in ceea ce priveste tehnica impachetarii materialelor supuse sterilizarii.

Utilizare
- EXPUNEREA - 134°C 3,5 min – 7 min sau 121°C timp minim de 15 minute
- Se plaseaza in interiorul pachetului sau recipientului pentru sterilizat in cele mai dificile zone
- DIMENSIUNI: L – 63 mm, l – 24 mm
- Initiati sterilizarea autoclav conform instructiunilor.
- Utilizarea indicatorilor chimici pentru monitorizarea internă se poate folosi in pachete, tăvi, recipiente și pungi. Indicatorii chimici ar trebui să fie utilizati în interiorul fiecare tip de ambalaj
- Este complet bazat pe apă și nu conține nici o substanță chimică.
- culoare de referință pentru interpretare rezultatelor pentru o sterilizare corecta (culoarea roz devine neagra) si este indicat pe indicatorul card. Nu expuneți acest produs la căldură uscată, EO, H2O2 sau orice alte procese de sterilizare în afară de abur.
- Timpul de producție și data expirării sunt plasate pe indicator.
- Indicatorul este în conformitate cu EN-ISO 11140.

Ambalare: 250 teste/cutie
Fiecare indicator este marcat: denumire produs, numarul de lot, data fabricatiei si data expirarii, clasa 5, standardul de conformitate cu ISO 11140-1.
Perioada de valabilitate
- indicatorii au o data de expirare de 5 ani de la data fabricatiei când conditiile de depozitare sunt cele recomandate
- Nu utilizați indicatori după data de expirare.
- dupa utilizare pastrati indicatorul 1 an in aceleasi conditii de temperatura si umiditate

VERIFICATION OF CONFORMITY

S/N: 001404

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

replaces **ICR Polska/VC/MH210103**

Name and address of Applicant
DÖRT-ATIP MALZEMELERİ SANAYİ İTHALAT İHRACAT TİCARET LİMİTED ŞİRKETİ
BALIKHİSAR MH. KÖYİÇİ SERPMELERİ NO:795/A AKYURT / ANKARA /TURKEY

Name and address of manufacturer:
DÖRT-ATIP MALZEMELERİ SANAYİ İTHALAT İHRACAT TİCARET LİMİTED ŞİRKETİ
BALIKHİSAR MH. KÖYİÇİ SERPMELERİ NO:795/A AKYURT / ANKARA /TURKEY

Product name and types:

- BANTLAR / TAPES:
  - BUHAR (CLASS I) / STEAM (CLASS I),
  - ETİLEN OKSİT (CLASS I) / ETHYLENE OXIDE (CLASS I),
  - FORMALDEHİT (CLASS I) / FORMALDEHYDE (CLASS I),
  - HİDROJEN PEROKSİT (CLASS I) / HYDROGEN PEROXIDE (CLASS I)
- İNDİKATOR KART STRİPLER / 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),
  - ETİLEN OKSİT (CLASS 5) / ETHYLENE OXIDE (CLASS 5),
  - HİDROJEN PEROKSİT(CLASS 4) / HYDROGEN PEROXIDE (CLASS 4),
  - FORMALDEHİT(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),
  - ETİLEN OKSİT (CLASS 1) / ETHYLENE OXIDE (CLASS 1),
  - FORMALDEHİT (CLASS 1) / FORMALDEHYDE (CLASS 1),
  - HİDROJEN PEROKSİT (CLASS 1) / HYDROGEN PEROXIDE (CLASS 1)

Product trademark: 4a medical® 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: partial report file
Tests conducted by: 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 series-production 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

Director: Rafał Kalinowski
Warsaw, 13.10.2021

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