



# EC CERTIFICATE

## Full Quality Assurance System

### Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : Dört A Tıp Malzemeleri San. İth. İhr. Tic. Ltd. Şti.  
Company Address : Balıkhisar Mah. Köyiçi Serpmeleri No:795/A Akyurt ANKARA / TURKEY  
Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)  
Product :  
- Sterile/ Non-sterile Polypropylene Mesh - Class IIb  
- Sterile/ Non-sterile Esu Pencil - Class IIb  
- Sterile/ Non-sterile T Drain - Class IIa  
- Sterile/ Non-sterile PVC Straight Drain (normal- blue x-ray line) - Class IIa  
- Sterile/ Non-sterile Silicone Straight Drain (normal- blue x-ray line) - Class IIa  
- Sterile/ Non-sterile PVC Thorax Drain (blue x-ray line) - Class IIa  
- Sterile/ Non-sterile Silicone Thorax Drain (blue x-ray line) - Class IIa  
- Sterile/ Non-sterile Flat Drain (normal/ blue x-ray line) - Class IIa  
- Sterile/ Non-sterile PVC Redon Drain (blue x-ray line) - Class IIa  
- Sterile/ Non-sterile Silicone Redon Drain (blue x-ray line) - Class IIa  
- Sterile/ Non-sterile Channel Drain (normal/ blue x-ray line) ( Flat/ round ) - Class IIa  
- Sterile/ Non-sterile Drain Suction Set (Yanquer Set ) With vacuum / Without vacuum - Class IIa  
- Sterile/ Non-sterile Penrose Drain (blue x-ray line) - Class IIa  
- Sterile/ Non-sterile Silicone Hemovac Drain Set Single/ Double - Class IIa  
- Sterile/ Non-sterile PVC Hemovac Drain Set Single / Double - Class IIa  
- Sterile/ Non-sterile Esu Pencil Cleaner - Class Is  
- Sterile/ Non-sterile Aspiration Tube - Class Is  
- Sterile/ Non-sterile Passive Chest Drainage Bottle 2000ml - Class Is  
- Sterile/ Non-sterile Bomb Reservoir - Class Is  
- Sterile/ Non-sterile Aspiration Handle (Yanquer Handle) (With vacuum / Without vacuum) - Class IIa

GMDN : 44681, 60300, 35824, 11305, 11301, 35917, 44643  
Certificate Number : M.2016.106.7276  
Report Number : MD.3334-YB  
Initial Assessment Date : 31.07.2012  
Registration Date : 05.12.2016  
Recertification Assessment Date : 30.11.2020  
Reissue Date : 29.04.2021/02  
Revision Date /No : -  
Expiry Date : 27.05.2024



UDEM International Certification  
Auditing Training Centre Industry  
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned



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## DECLARATION OF CONFORMITY

We, DÖRT-A TIP MALZEMELERİ SANAYİ İTHALAT İHRACAT TİCARET LİMİTED ŞİRKETİ, declare that the following products are in compliance with the provisions of the Council Directive 2017/745 for medical devices. All supporting documents are stored within the manufacturer. We declare that we will fulfill the obligations imposed by the quality system and that we will maintain the quality system adequately and effectively.

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

**ADDRESS:** Balıkhisar Mah. Köyüçü Serpmeleri No:795/A AKYURT/ ANKARA Turkey

**Products:** Sterilization Reels and Pouches (Flat, Gusset, Tyvek), Flat and Self Sealing Sterilization Pouches, SMS Paper, Crepe Paper

**Class:** Class-I Nonsteril Products-ANNEX VIII

**BASIC UDI-DI :** 868082970SG3

**BASIC UDI-DI :** 869744275SJD

**BASIC UDI-DI :** 86811764SW2

The products depicted above comply with the following directives.

<b>DOCUMENT NO</b>	<b>TITLE</b>	<b>PRINT DATE OF REGULATION</b>
2017/745/MDR	Annex IV of the 2017/745/Council Directive on Medical Directives	25.05.2017
TS EN 868-5	Packaging Materials	28.01.2019
TS EN 868-9	Packaging Materials	28.01.2019
TS EN 11607-1	Packaging Materials	09.11.2020
TS EN 11607-2	Packaging Materials	09.11.2020

<b>Primary Product Number</b>	<b>Product Name</b>	<b>BASIC UDI-DI</b>
8680829700019	SMS Paper 500 x 500 mm	868082970SG3
8680829700026	SMS Paper 600 x 600 mm	868082970SG3
8680829700040	SMS Paper 900 x 900 mm	868082970SG3
8680829700057	SMS Paper 1000 x 1000 mm	868082970SG3
8680829700064	SMS Paper 1200 x 1200 mm	868082970SG3
8680829700095	Sterilization Gusset Reel 200 mm x 60 mm x 100 m, 70g 2 Indicators	868082970SG3
8680829700101	Tyvek Reel 300 mm x 70 m	868082970SG3
8680829700118	Sterilization Flat Reel 250 mm x 200 m, 60g 2 Indicators	868082970SG3
8680829700125	Sterilization Pouch 100 mm x 300 mm	868082970SG3
8680829700132	Sterilization Pouch 100 mm x 150 mm	868082970SG3
8680829700149	Sterilization Pouch 150 mm x 300 mm Gusset	868082970SG3
8680829700156	Sterilization Pouch 100 mm x 300 mm Gusset	868082970SG3
8680829700163	Sterilization Pouches 70 mm x 255 mm	868082970SG3
8680829700170	Sterilization Pouches 90 mm x 255 mm	868082970SG3
8680829700187	Sterilization Reel Without Print 75 mm x 200 m	868082970SG3
8680829700194	Sterilization Gusset Reel 500 mm x 80 mm x 100 m, 70g 2 Indicators	868082970SG3
8680829700200	Sterilization Flat Reel 400 mm x 200 m, 70g 2 Indicators	868082970SG3
8680829700217	Sterilization Pouch 90 mm x 230 mm	868082970SG3
8680829700224	Tyvek Reel 200 mm x 70 m	868082970SG3
8680829700231	Sterilization Flat Reel 420 mm x 200 m, 70g 2 Indicators	868082970SG3



8680829700262	Sterilization Flat Reel 450 mm x 200 m, 60g 3 Indicators	868082970SG3
8680829700279	Sterilization Gusset Reel 500 mm x 85 mm x 100 m, 60g 2 Indicators	868082970SG3
8680829700293	Sterilization Gusset Reel 100 mm 50 mm x 100 m, 70g 2 Indicators	868082970SG3
8680829700316	Sterilization Gusset Reel 400 mm x 80 mm 100 m, 70g 3 Indicators	868082970SG3
8680829700323	Tyvek Reel 120 mm x 70 m	868082970SG3
8680829700330	Sterilization Pouch 170 mm x 340 mm	868082970SG3
8680829700347	Sterilization Flat Reel 120 mm x 200 m, 60g 2 Indicators	868082970SG3
8680829704000	Tyvek Reel 250 mm x 70 m	868082970SG3
8680829707117	Sterilization Flat Reel 450 mm x 200 m, 70g 3 Indicators	868082970SG3
8680829707599	Sterilization Flat Reel 500 mm x 200 m, 70g 3 Indicators	868082970SG3
8681176422517	Sterilization Flat Reel 450 mm x 200 m, 60g 2 Indicators	86811764SW2
8681176422524	Sterilization Flat Reel 450 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176422531	Sterilization Flat Reel 500 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176422548	Sterilization Gusset Reel 500 mm x 80 mm x 100 m, 60g 2 Indicators	86811764SW2
8681176422555	Sterilization Gusset Reel 450 mm x 80 mm x 100 m, 60g 3 Indicators	86811764SW2
8681176422562	Sterilization Gusset Reel 500 mm x 80 mm x 100 m, 60g 3 Indicators	86811764SW2
8681176422579	Sterilization Gusset Reel 450 mm x 80 mm x 100 m, 70g 2 Indicators	86811764SW2
8681176422586	Sterilization Gusset Reel 500 mm x 80 mm x 100 m, 70g 2 Indicators	86811764SW2
8681176422593	Sterilization Gusset Reel 450 mm x 80 mm x 100 m, 70g 3 Indicators	86811764SW2
8681176422609	Sterilization Gusset Reel 500 mm x 80 mm x 100 m, 70g 3 Indicators	86811764SW2
8681176422616	Sterilization Gusset Reel 200 mm x 50 mm x 100 m 60 g 2 Indicators	86811764SW2
8681176422623	Düz Sterilizasyon Rulosu 500 mm x 200 m 60gr 2 Indicators	86811764SW2
8681176422630	Sterilization Reel 500 mm x 200 m 70gr. 2 Indicators	86811764SW2
8681176422647	Sterilization Reel 500 mm x 200 m 70gr. 2 Indicators	86811764SW2
8681176422654	Sterilization Pouches	86811764SW2
8681176422661	Sterilization Reel 450 mm x 200 m	86811764SW2
8681176422678	Sterilization Reel 500 mm x 200 m	86811764SW2
8681176422685	SMS Paper	86811764SW2

8681176422692	Crepe Paper	86811764SW2
8681176413027	Sterilization Pouch 150 mm x 210 mm	86811764SW2
8681176413034	Sterilization Flat Reel 400 mm x 200 m, 60g 2 Indicators	86811764SW2
8681176413041	Sterilization Pouch 150 mm x 350 mm	86811764SW2
8681176413058	Sterilization Gusset Reel 350 mm x 75 mm x 100 m, 60g 2 Indicators	86811764SW2
8681176413065	Sterilization Pouch 90 mm x 230 mm	86811764SW2
8681176413072	Sterilization Gusset Reel 75 mm x 45 mm x 100 m, 60g 2 Indicators	86811764SW2
8681176413867	Sterilization Flat Reel 100 mm x 200 m, 70g 2 Indicators	86811764SW2
8681176413874	Sterilization Gusset Reel 100 mm x 50 mm x 100 m, 60g 2 Indicators	86811764SW2
8681176413881	Sterilization Pouches	86811764SW2
8681176413935	Sterilization Pouches 100 mm x 300 mm	86811764SW2
8681176413942	Sterilization Pouch 90 mm x 150 mm	86811764SW2
8681176413966	Sterilization Flat Reel 500 mm x 200 m, 60g 2 Indicators	86811764SW2
8681176413973	Sterilization Flat Reel 75 mm x 200 m, 70g 2 Indicators	86811764SW2
8681176413980	Sterilization Flat Reel 450 mm x 200 m, 60g 2 Indicators	86811764SW2
8681176413997	Sterilization Reel Without Print 250 mm x 200 m	86811764SW2
8681176414000	Sterilization Gusset Reel 120 mm x 55 mm x 100 m, 70g 2 Indicators	86811764SW2
8681176414017	Sterilization Pouches 150 mm x 200 mm	86811764SW2
8681176414024	Sterilization Pouch 150 mm x 200 mm	86811764SW2
8681176414031	Sterilization Pouch 200 mm x 260 mm	86811764SW2
8681176414048	Sterilization Flat Reel 150 mm x 200 m, 70g 2 Indicators	86811764SW2
8681176414055	Sterilization Pouches 150 mm x 250 mm	86811764SW2
8681176414062	Sterilization Pouches 150 mm x 400 mm	86811764SW2
8681176414079	Sterilization Reel 500 mm x 200 m	86811764SW2
8681176414086	Sterilization Gusset Reel 450 mm x 80 mm 100 m, 70g 2 Indicators	86811764SW2
8681176414093	Sterilization Flat Reel 250 mm x 200 m, 70g 2 Indicators	86811764SW2
8681176414116	Sterilization Gusset Reel 500 mm x 80 mm x 100 m, 60g 2 Indicators	86811764SW2
8681176414123	Sterilization Flat Reel 400 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176414130	Tyvek Reel 300 mm x 70 m	86811764SW2
8681176414147	Sterilization Flat Reel 450 mm x 200 m, 70g 2 Indicators	86811764SW2
8681176414154	Sterilization Gusset Reel 450 mm x 80 mm x 100 m, 70g 2 Indicators	86811764SW2

8681176414161	Sterilization Gusset Reel 150 mm x 55 mm x 100 m, 60g 2 Indicators	86811764SW2
8681176414178	Sterilization Flat Reel 120 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176414192	Sterilization Flat Reel 500 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176414215	Sterilization Reel Without Print 420 mm x 200 m	86811764SW2
8681176414222	Sterilization Gusset Reel 150 mm x 55 mm x 100 m, 70g 2 Indicators	86811764SW2
8681176414253	Tyvek Reel 400 mm x 70 m	86811764SW2
8681176414260	Sterilization Gusset Reel 100 mm x 50 mm x 100 m, 70g 3 Indicators	86811764SW2
8681176414277	Sterilization Gusset Reel 400 mm x 80 mm x 100 m, 70g 2 Indicators	86811764SW2
8681176414284	Sterilization Flat Reel 300 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176414291	Sterilization Pouches 300 mm x 300 mm	86811764SW2
8681176414307	Sterilization Flat Reel 450 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176414314	Sterilization Gusset Reel 250 mm x 65 mm x 100 m, 60g 2 Indicators	86811764SW2
8681176414321	Sterilization Reel Without Print 400 mm x 200 m	86811764SW2
8681176414338	Sterilization Reel Without Print 300 mm x 200 m	86811764SW2
8681176414345	Sterilization Flat Reel 200 mm x 200 m , 70g 3 Indicators	86811764SW2
8681176414352	Sterilization Gusset Reel 120 mm x 55 mm x 100 m, 60g 2 Indicators	86811764SW2
8681176414420	Sterilization Flat Reel 50 mm x 200 m, 70g 2 Indicators	86811764SW2
8681176414437	Sterilization Pouch 200 mm x 460 mm	86811764SW2
8681176414444	Sterilization Gusset Reel 300 mm x 70 mm x 100 m , 70g 2 Indicators	86811764SW2
8681176414451	Sterilization Reel Without Print 450 mm x 200 m	86811764SW2
8681176414468	Sterilization Flat Reel 50 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176414475	Sterilization Gusset Reel 450 mm x 80 mm x 100 m, 60g 3 Indicators	86811764SW2
8681176414482	Sterilization Gusset Reel 500 mm x 80 mm x 100 m, 70g 3 Indicators	86811764SW2
8681176414499	Tyvek Reel 250 mm x 70 m	86811764SW2
8681176414512	Sterilization Pouch 250 mm x 300 mm	86811764SW2
8681176414529	Sterilization Gusset Reel 75 mm x 45 mm x 100 m , 60g 3 Indicators	86811764SW2
8681176414536	Sterilization Gusset Reel 450 mm x 80 mm x 100 m, 60g 3 Indicators	86811764SW2
8681176414543	Sterilization Gusset Reel 250 mm x 65 mm x 100 m, 60g 3 Indicators	86811764SW2
8681176414567	Sterilization Flat Reel 350 mm x 200 m, 60g 2 Indicators	86811764SW2

8681176414581	Sterilization Gusset Reel 350 mm x 75 mm x 100 m, 70g 2 Indicators	86811764SW2
8681176414598	Sterilization Pouch 150 mm x 250 mm	86811764SW2
8681176414611	Sterilization Reel Without Print 120 mm x 200 m	86811764SW2
8681176414628	Sterilization Gusset Reel 200 mm x 60 mm x 100 m, 60g 3 Indicators	86811764SW2
8681176414635	Tyvek Reel 400 mm x 70 m	86811764SW2
8681176414642	Sterilization Pouch 100 mm x 200 mm	86811764SW2
8681176414659	Sterilization Reel 500 mm x 200 m 70gr. 2 Indicators	86811764SW2
8681176414666	Sterilization Gusset Reel 100 mm x 50 mm x 100 m, 60g 3 Indicators	86811764SW2
8681176414680	Sterilization Gusset Reel 250 mm x 65 mm x 100 m, 70g 3 Indicators	86811764SW2
8681176414703	Sterilization Flat Reel 400 mm x 200 m, 70g 3 Indicators	86811764SW2
8681176414710	Tyvek Reel 500 mm x 70 m	86811764SW2
8681176415113	Sterilization Flat Reel 200 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176415120	Sterilization Flat Reel 300 mm x 200 m, 60g 2 Indicators	86811764SW2
8681176415137	Sterilization Gusset Reel 400 mm x 80 mm x 100 m, 60g 2 Indicators	86811764SW2
8681176415144	Sterilization Pouch 150 mm x 340 mm	86811764SW2
8681176415151	Sterilization Flat Reel 420 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176415281	Sterilization Flat Reel 75 mm x 200 m, 60g 2 Indicators	86811764SW2
8681176415298	Sterilization Gusset Reel 75 mm x 45 mm x 100 m, 70g 2 Indicators	86811764SW2
8681176415304	Sterilization Pouch 250 mm x 430 mm	86811764SW2
8681176415311	Sterilization Gusset Reel 420 mm x 80 mm x 100 m, 60g 3 Indicators	86811764SW2
8681176415328	Sterilization Pouches 200 mm x 30 mm	86811764SW2
8681176415335	Sterilization Gusset Reel 450 mm x 80 mm x 100 m, 70g 3 Indicators	86811764SW2
8681176415342	Sterilization Gusset Reel 450 mm x 80 mm x 100 m, 70g 3 Indicators	86811764SW2
8681176415359	Sterilization Pouches 150 mm x 300 mm	86811764SW2
8681176415366	Sterilization Pouches 200 mm x 400 mm	86811764SW2
8681176415380	Tyvek Reel 200 mm x 70 m	86811764SW2
8681176415397	Tyvek Reel 75 mm x 70 m	86811764SW2
8681176415403	Sterilization Reel Without Print 500 mm x 200 m	86811764SW2
8681176415410	Sterilization Reel Without Print 200 mm x 200 m	86811764SW2
8681176415434	Sterilization Gusset Reel 120 mm x 55 mm x 100 m, 60g 3 Indicators	86811764SW2
8681176415441	Sterilization Reel Without Print 50 mm x 200 m	86811764SW2

8681176415458	Sterilization Flat Reel 150 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176415465	Sterilization Pouches 200 mm x 200 mm	86811764SW2
8681176415472	Tyvek Reel 300 mm x 70 m	86811764SW2
8681176415489	Sterilization Gusset Reel 420 mm x 80 mm x 100 m, 70g 2 Indicators	86811764SW2
8681176415496	Sterilization Reel Without Print 350 mm x 200 m	86811764SW2
8681176415502	Tyvek Reel 100 mm x 70 m	86811764SW2
8681176415519	Sterilization Flat Reel 250 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176415526	Sterilization Reel 500 mm x 200 m, 70gr. 2 Indicators	86811764SW2
8681176415533	Sterilization Pouches 150 mm x 150 mm	86811764SW2
8681176415540	Sterilization Gusset Reel 150 mm x 55 mm x 100 m, 60g 3 Indicators	86811764SW2
8681176415557	Sterilization Reel Without Print 100 mm x 200 m	86811764SW2
8681176415571	Sterilization Flat Reel 350 mm x 200 m, 70g 3 Indicators	86811764SW2
8681176415588	Sterilization Flat Reel 420 mm x 200 m, 70g 3 Indicators	86811764SW2
8681176415595	Sterilization Flat Reel 50 mm x 200 m, 70g 3 Indicators	86811764SW2
8681176415601	Sterilization Gusset Reel 500 mm x 80 mm x 100 m, 70g 2 Indicators	86811764SW2
8681176415618	Sterilization Pouches 300 mm x 400 mm	86811764SW2
8681176415625	Sterilization Gusset Reel 500 mm x 80 mm x 100 m, 70g 3 Indicators	86811764SW2
8681176415632	Tyvek Reel 100 mm x 70 m	86811764SW2
8681176415649	Düz Sterilizasyon Rulosu 500 mm x 200 m, 60gr 2 Indicators	86811764SW2
8681176415656	Tyvek Reel 50 mm x 70 m	86811764SW2
8681176415663	Sterilization Flat Reel 75 mm x 200 m, 70g 3 Indicators	86811764SW2
8681176415670	Sterilization Flat Reel 500 mm x 200 m, 70g 2 Indicators	86811764SW2
8681176415687	Sterilization Gusset Reel 500 mm x 80 mm x 100 m, 60g 3 Indicators	86811764SW2
8681176415694	Sterilization Gusset Reel 300 mm x 70 mm x 100 m, 60g 3 Indicators	86811764SW2
8681176415717	Sterilization Pouch 70 mm x 230 mm	86811764SW2
8681176415724	Sterilization Flat Reel 350 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176415731	Sterilization Gusset Reel 350 mm x 75 mm x 100 m, 70g 3 Indicators	86811764SW2
8681176415748	Sterilization Gusset Reel 400 mm x 80 mm x 100 m, 60g 3 Indicators	86811764SW2
8681176415755	Sterilization Flat Reel 450 mm x 200 m, 60g 2 Indicators	86811764SW2



8681176415779	Sterilization Flat Reel 250 mm x 200 m, 70g 3 Indicators	86811764SW2
8681176415786	Sterilization Pouch 250 mm x 540 mm	86811764SW2
8681176415793	Sterilization Flat Reel 150 mm x 200 m, 60g 2 Indicators	86811764SW2
8681176415809	Sterilization Flat Reel 120 mm x 200 m, 70g 2 Indicators	86811764SW2
8681176415816	Tyvek Reel 350 mm x 70 m	86811764SW2
8681176415823	Sterilization Flat Reel 100 mm x 200 m, 60g 2 Indicators	86811764SW2
8681176415830	Sterilization Flat Reel 120 mm x 200 m, 70g 3 Indicators	86811764SW2
8681176415847	Sterilization Flat Reel 300 mm x 200 m, 70g 3 Indicators	86811764SW2
8681176415854	Sterilization Flat Reel 200 mm x 200 m, 60g 2 Indicators	86811764SW2
8681176415861	Sterilization Flat Reel 200 mm x 200 m, 70g 2 Indicators	86811764SW2
8681176415878	Sterilization Gusset Reel 200 mm x 50 mm x 100 m 60 g 2 Indicators	86811764SW2
8681176415885	Sterilization Flat Reel 500 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176415892	Sterilization Gusset Reel 75 mm x 45 mm x 100 m, 70g 3 Indicators	86811764SW2
8681176415908	Sterilization Flat Reel 150 mm x 200 m, 70g 3 Indicators	86811764SW2
8681176415915	Sterilization Reel Without Print 150 mm x 200 m	86811764SW2
8681176415922	Sterilization Gusset Reel 250 mm x 65 mm x 100 m, 70g 2 Indicators	86811764SW2
8681176415939	Sterilization Flat Reel 300 mm x 200 m, 70g 2 Indicators	86811764SW2
8681176415946	Tyvek Reel 75 mm x 70 m	86811764SW2
8681176415960	Sterilization Gusset Reel 120 mm x 55 mm x 100 m, 70g 3 Indicators	86811764SW2
8681176420568	Sterilization Flat Reel 75 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420575	Tyvek Reel 350 mm x 70 m	86811764SW2
8681176420582	Tyvek Reel 300 mm x 70 m	86811764SW2
8681176420599	Tyvek Reel 400 mm x 70 m	86811764SW2
8681176420605	Sterilization Flat Reel 50 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420612	Tyvek Reel 250 mm x 70 m	86811764SW2
8681176420629	Tyvek Reel 200 mm x 70 m	86811764SW2
8681176420636	Tyvek Reel 75 mm x 70 m	86811764SW2
8681176420643	Sterilization Flat Reel 150 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420650	Tyvek Reel 100 mm x 70 m	86811764SW2
8681176420667	Tyvek Reel 50 mm x 70 m	86811764SW2

8681176420674	Sterilization Flat Reel 100 mm x 200 m , 60g 3 Ind.	86811764SW2
8681176420681	Tyvek Reel 150 mm x 70 m	86811764SW2
8681176420698	Sterilization Flat Reel 350 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420704	Sterilization Flat Reel 300 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420711	Sterilization Flat Reel 250 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420728	Sterilization Flat Reel 200 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420735	Sterilization Flat Reel 400 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420773	Sterilization Flat Reel 380 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420872	Sterilization Flat Reel 430 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420889	Sterilization Flat Reel 250 mm x 100 m, 60g 3 Indicators	86811764SW2
8681176420902	Sterilization Flat Reel 210 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420919	Sterilization Flat Reel 450 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420926	Sterilization Flat Reel 500 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420933	Sterilization Flat Reel 430 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420940	Sterilization Flat Reel 600 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176420957	Sterilization Flat Reel 50 mm x 100 m 60g 3 Indicators	86811764SW2
8681176420964	Sterilization Flat Reel 75 mm x 100 m 60g 3 Indicators	86811764SW2
8681176420971	Sterilization Flat Reel 100 mm x 100 m 60g 3 Indicators	86811764SW2
8681176420988	Sterilization Flat Reel 120 mm x 100 m 60g 3 Indicators	86811764SW2
8681176420995	Sterilization Flat Reel 150 mm x 100 m 60g 3 Indicators	86811764SW2
8681176421008	Sterilization Flat Reel 200 mm x 100 m 60g 3 Indicators	86811764SW2
8681176421015	Sterilization Flat Reel 250 mm x 100 m 60g 3 Indicators	86811764SW2
8681176421022	Sterilization Flat Reel 300 mm x 100 m 60g 3 Indicators	86811764SW2
8681176421039	Sterilization Flat Reel 350 mm x 100 m 60g 3 Indicators	86811764SW2
8681176421046	Sterilization Flat Reel 400 mm x 100 m 60g 3 Indicators	86811764SW2

8681176421053	Sterilization Flat Reel 450 mm x 100 m 60g 3 Indicators	86811764SW2
8681176421060	Sterilization Flat Reel 500 mm x 100 m 60g 3 Indicators	86811764SW2
8681176421077	Sterilization Flat Reel 600 mm x 100 m 60g 3 Indicators	86811764SW2
8681176421084	Tyvek Reel 75 mm x 100 m	86811764SW2
8681176421091	Tyvek Reel 100 mm x 100 m	86811764SW2
8681176421107	Tyvek Reel 120 mm x 100 m	86811764SW2
8681176421114	Tyvek Reel 150 mm x 100 m	86811764SW2
8681176421121	Tyvek Reel 200 mm x 100 m	86811764SW2
8681176421138	Tyvek Reel 250 mm x 100 m	86811764SW2
8681176421145	Tyvek Reel 300 mm x 100 m	86811764SW2
8681176421152	Tyvek Reel 350 mm x 100 m	86811764SW2
8681176421169	Tyvek Reel 400 mm x 100 m	86811764SW2
8681176421176	Tyvek Reel 450 mm x 100 m	86811764SW2
8681176421183	Tyvek Reel 500 mm x 100 m	86811764SW2
8681176421336	Sterilization Flat Pouch	86811764SW2
8681176421343	Sterilization Self Sealing Pouch	86811764SW2
8681176421350	Sterilization Gusset Pouch	86811764SW2
8681176421367	Tyvek Pouch	86811764SW2
8681176421374	Reinforced Self Sealing Pouch	86811764SW2
8681176421381	Reinforced Flat Pouch	86811764SW2
8681176421442	Crepe Paper 350 x 350 mm	86811764SW2
8681176421459	Crepe Paper 400 x 400 mm	86811764SW2
8681176421466	SMS Paper 300 x 300 mm	86811764SW2
8681176421473	SMS Paper 350 x 350 mm	86811764SW2
8681176421480	SMS Paper 400 x 400 mm	86811764SW2
8681176421497	SMS Paper 750 x 750 mm	86811764SW2
8681176421572	Tyvek Reel 125 mm x 70 m	86811764SW2
8681176421763	Sterilization Flat Reel 600 mm x 200 m, 60g 2 Indicators	86811764SW2
8681176421770	Sterilization Flat Reel 800 mm x 200 m, 60g 2 Indicators	86811764SW2
8681176421787	Sterilization Flat Reel 600 mm x 200 m, 60g 3 Indicators	86811764SW2
8681176421794	Sterilization Flat Reel 800 mm x 200 m, 60g 3 Indicators	86811764SW2
8697442750017	Sterilization Flat Reel 50 mm x 200 m, 60g 2 Indicators	869744275SJD
8697442750024	Sterilization Flat Reel 75 mm x 200 m, 60g 2 Indicators	869744275SJD
8697442750031	Sterilization Flat Reel 100 mm x 200 m, 60g 2 Indicators	869744275SJD
8697442750048	Sterilization Flat Reel 120 mm x 200 m, 60g 2 Indicators	869744275SJD

8697442750055	Sterilization Flat Reel 150 mm x 200 m, 60g 2 Indicators	869744275SJD
8697442750062	Sterilization Flat Reel 200 mm x 200 m, 60g 2 Indicators	869744275SJD
8697442750079	Sterilization Flat Reel 250 mm x 200 m, 60g 2 Indicators	869744275SJD
8697442750086	Sterilization Flat Reel 300 mm x 200 m, 60g 2 Indicators	869744275SJD
8697442750093	Sterilization Flat Reel 350 mm x 200 m, 60g 2 Indicators	869744275SJD
8697442750109	Sterilization Flat Reel 400 mm x 200 m, 60g 2 Indicators	869744275SJD
8697442750116	Sterilization Flat Reel 420 mm x 200 m, 60g 2 Indicators	869744275SJD
8697442750123	Sterilization Gusset Reel 75 mm x 45 mm x 100 m, 60g 2 Indicators	869744275SJD
8697442750130	Sterilization Gusset Reel 100 mm x 50 mm x 100 m, 60g 2 Indicators	869744275SJD
8697442750147	Sterilization Gusset Reel 120 mm x 55 mm x 100 m, 60g 2 Indicators	869744275SJD
8697442750154	Sterilization Gusset Reel 150 mm x 55 mm x 100 m, 60g 2 Indicators	869744275SJD
8697442750178	Sterilization Gusset Reel 250 mm x 65 mm x 100 m, 60g 2 Indicators	869744275SJD
8697442750185	Sterilization Gusset Reel 300 mm x 70 mm x 100 m, 60g 2 Indicators	869744275SJD
8697442750192	Sterilization Gusset Reel 350 mm x 75 mm x 100 m, 60g 2 Indicators	869744275SJD
8697442750208	Sterilization Gusset Reel 400 mm x 80 mm x 100 m, 60g 2 Indicators	869744275SJD
8697442750215	Sterilization Gusset Reel 420 mm x 80 mm x 100 m, 60g 2 Indicators	869744275SJD
8697442750222	Sterilization Flat Reel 50 mm x 200 m, 60g 3 Indicators	869744275SJD
8697442750239	Sterilization Flat Reel 75 mm x 200 m, 60g 3 Indicators	869744275SJD
8697442750246	Sterilization Flat Reel 100 mm x 200 m, 60g 3 Indicators	869744275SJD
8697442750253	Sterilization Flat Reel 120 mm x 200 m, 60g 3 Indicators	869744275SJD
8697442750260	Sterilization Flat Reel 150 mm x 200 m, 60g 3 Indicators	869744275SJD
8697442750277	Sterilization Flat Reel 200 mm x 200 m, 60g 3 Indicators	869744275SJD
8697442750284	Sterilization Flat Reel 250 mm x 200 m, 60g 3 Indicators	869744275SJD
8697442750291	Sterilization Flat Reel 300 mm x 200 m, 60g 3 Indicators	869744275SJD
8697442750307	Sterilization Flat Reel 350 mm x 200 m, 60g 3 Indicators	869744275SJD

8697442750314	Sterilization Flat Reel 400 mm x 200 m, 60g 3 Indicators	869744275SJD
8697442750321	Sterilization Flat Reel 420 mm x 200 m, 60g 3 Indicators	869744275SJD
8697442750338	Sterilization Gusset Reel 75 mm x 45 mm x 100 m, 60g 3 Indicators	869744275SJD
8697442750345	Sterilization Gusset Reel 100 mm x 50 mm x 100 m, 60g 3 Indicators	869744275SJD
8697442750352	Sterilization Gusset Reel 120 mm x 55 mm x 100 m, 60g 3 Indicators	869744275SJD
8697442750369	Sterilization Gusset Reel 150 mm x 55 mm x 100 m, 60g 3 Indicators	869744275SJD
8697442750376	Sterilization Gusset Reel 200 mm x 60 mm x 100 m, 60g 3 Indicators	869744275SJD
8697442750383	Sterilization Gusset Reel 250 mm x 65 mm x 100 m, 60g 3 Indicators	869744275SJD
8697442750390	Sterilization Gusset Reel 300 mm x 70 mm x 100 m, 60g 3 Indicators	869744275SJD
8697442750406	Sterilization Gusset Reel 350 mm x 75 mm x 100 m, 60g 3 Indicators	869744275SJD
8697442750413	Sterilization Gusset Reel 400 mm x 80 mm x 100 m, 60g 3 Indicators	869744275SJD
8697442750420	Sterilization Gusset Reel 420 mm x 80 mm x 100 m, 60g 3 Indicators	869744275SJD
8697442750437	Sterilization Flat Reel 50 mm x 200 m, 70g 2 Indicators	869744275SJD
8697442750444	Sterilization Flat Reel 75 mm x 200 m, 70g 2 Indicators	869744275SJD
8697442750451	Sterilization Flat Reel 100 mm x 200 m, 70g 2 Indicators	869744275SJD
8697442750468	Sterilization Flat Reel 120 mm x 200 m, 70g 2 Indicators	869744275SJD
8697442750475	Sterilization Flat Reel 150 mm x 200 m, 70g 2 Indicators	869744275SJD
8697442750482	Sterilization Flat Reel 200 mm x 200 m, 70g 2 Indicators	869744275SJD
8697442750499	Sterilization Flat Reel 250 mm x 200 m, 70g 2 Indicators	869744275SJD
8697442750505	Sterilization Flat Reel 300 mm x 200 m, 70g 2 Indicators	869744275SJD
8697442750512	Sterilization Flat Reel 350 mm x 200 m, 70g 2 Indicators	869744275SJD
8697442750529	Sterilization Flat Reel 400 mm x 200 m, 70g 2 Indicators	869744275SJD
8697442750536	Sterilization Flat Reel 420 mm x 200 m, 70g 2 Indicators	869744275SJD
8697442750543	Sterilization Gusset Reel 75 mm x 45 mm x 100 m, 70g 2 Indicators	869744275SJD
8697442750550	Sterilization Gusset Reel 100 mm x 50 mm x 100 m, 70g 2 Indicators	869744275SJD

8697442750567	Sterilization Gusset Reel 120 mm x 55 mm x 100 m, 70g 2 Indicators	869744275SJD
8697442750574	Sterilization Gusset Reel 150 mm x 55 mm x 100 m, 70g 2 Indicators	869744275SJD
8697442750598	Sterilization Gusset Reel 250 mm x 65 mm x 100 m, 70g 2 Indicators	869744275SJD
8697442750604	Sterilization Gusset Reel 300 mm x 70 mm x 100 m, 70g 2 Indicators	869744275SJD
8697442750611	Sterilization Gusset Reel 350 mm x 75 mm x 100 m, 70g 2 Indicators	869744275SJD
8697442750628	Sterilization Gusset Reel 400 mm x 80 mm x 100 m, 70g 2 Indicators	869744275SJD
8697442750635	Sterilization Gusset Reel 420 mm x 80 mm x 100 m, 70g 2 Indicators	869744275SJD
8697442750642	Sterilization Flat Reel 50 mm x 200 m, 70g 3 Indicators	869744275SJD
8697442750659	Sterilization Flat Reel 75 mm x 200 m, 70g 3 Indicators	869744275SJD
8697442750666	Sterilization Flat Reel 100 mm x 200 m, 70g 3 Indicators	869744275SJD
8697442750673	Sterilization Flat Reel 120 mm x 200 m, 70g 3 Indicators	869744275SJD
8697442750680	Sterilization Flat Reel 150 mm x 200 m, 70g 3 Indicators	869744275SJD
8697442750697	Sterilization Flat Reel 200 mm x 200 m, 70g 3 Indicators	869744275SJD
8697442750703	Sterilization Flat Reel 250 mm x 200 m, 70g 3 Indicators	869744275SJD
8697442750710	Sterilization Flat Reel 300 mm x 200 m, 70g 3 Indicators	869744275SJD
8697442750727	Sterilization Flat Reel 350 mm x 200 m, 70g 3 Indicators	869744275SJD
8697442750734	Sterilization Flat Reel 400 mm x 200 m, 70g 3 Indicators	869744275SJD
8697442750741	Sterilization Flat Reel 420 mm x 200 m, 70g 3 Indicators	869744275SJD
8697442750758	Sterilization Gusset Reel 75 mm x 45 mm x 100 m, 70g 3 Indicators	869744275SJD
8697442750765	Sterilization Gusset Reel 100 mm x 50 mm x 100 m, 70g 3 Indicators	869744275SJD
8697442750772	Sterilization Gusset Reel 120 mm x 55 mm x 100 m, 70g 3 Indicators	869744275SJD
8697442750789	Sterilization Gusset Reel 150 mm x 55 mm x 100 m, 70g 3 Indicators	869744275SJD
8697442750796	200 mm x 60 mm x 100 m, 70g 3 Ind. Sterilization Gusset Reel	869744275SJD
8697442750802	Sterilization Gusset Reel 250 mm x 65 mm x 100 m, 70g 3 Indicators	869744275SJD
8697442750819	Sterilization Gusset Reel 300 mm x 70 mm x 100 m, 70g 3 Indicators	869744275SJD



8697442750826	Sterilization Gusset Reel 350 mm x 75 mm x 100 m, 70g 3 Indicators	869744275SJD
8697442750833	Sterilization Gusset Reel 400 mm x 80 mm x 100 m, 70g 3 Indicators	869744275SJD
8697442750840	Sterilization Gusset Reel 420 mm x 80 mm x 100 m, 70g 3 Indicators	869744275SJD
8697442750949	Tyvek Sterilization Reel 500 mm x 70 m	869744275SJD
8697442750970	Crepe Paper 500 x 500 mm	869744275SJD
8697442750987	Crepe Paper 600 x 600 mm	869744275SJD
8697442750994	Crepe Paper 750 x 750 mm	869744275SJD
8697442751007	Crepe Paper 900 x 900 mm	869744275SJD
8697442751014	Crepe Paper 1000 x 1000 mm	869744275SJD
8697442751021	Crepe Paper 1200 x 1200 mm	869744275SJD
8697442751038	Sterilization Reel Without Print 50 mm x 200 m	869744275SJD
8697442751045	Sterilization Reel Without Print 75 mm x 200 m	869744275SJD
8697442751052	Sterilization Reel Without Print 100 mm x 200 m	869744275SJD
8697442751069	Sterilization Reel Without Print 120 mm x 200 m	869744275SJD
8697442751076	Sterilization Reel Without Print 150 mm x 200 m	869744275SJD
8697442751083	Sterilization Reel Without Print 200 mm x 200 m	869744275SJD
8697442751090	Sterilization Reel Without Print 250 mm x 200 m	869744275SJD
8697442751106	Sterilization Reel Without Print 300 mm x 200 m	869744275SJD
8697442751113	Sterilization Reel Without Print 350 mm x 200 m	869744275SJD
8697442751120	Sterilization Reel Without Print 400 mm x 200 m	869744275SJD
8697442751137	Sterilization Reel Without Print 420 mm x 200 m	869744275SJD
8697442754978	Tyvek Sterilization Reel 75 mm x 70 m	869744275SJD
8697442754985	Tyvek Sterilization Reel 100 mm x 70 m	869744275SJD
8697442755005	Tyvek Sterilization Reel 150 mm x 70 m	869744275SJD
8697442755012	Tyvek Sterilization Reel 200 mm x 70 m	869744275SJD
8697442755029	Tyvek Sterilization Reel 250 mm x 70 m	869744275SJD
8697442755036	Tyvek Sterilization Reel 300 mm x 70 m	869744275SJD
8697442755043	Tyvek Sterilization Reel 350 mm x 70 m	869744275SJD
8697442755050	Tyvek Sterilization Reel 400 mm x 70 m	869744275SJD
8697442755128	Crepe Paper 150 x 200 mm	869744275SJD
8697442755685	Tyvek Reel 50 mm x 70 m	869744275SJD
8697442755692	Tyvek Reel 75 mm x 70 m	869744275SJD
8697442755708	Tyvek Reel 100 mm x 70 m	869744275SJD
8697442755715	Tyvek Reel 120 mm x 70 m	869744275SJD
8697442755722	Tyvek Reel 150 mm x 70 m	869744275SJD
8697442755739	Tyvek Reel 200 mm x 70 m	869744275SJD
8697442755746	Tyvek Reel 250 mm x 70 m	869744275SJD
8697442755760	Tyvek Reel 350 mm x 70 m	869744275SJD
8697442755777	Tyvek Reel 400 mm x 70 m	869744275SJD
8697442757092	Sterilization Flat Reel 450 mm x 200 m, 60g 2 Indicators	869744275SJD
8697442757108	Sterilization Flat Reel 500 mm x 200 m, 60g 2 Indicators	869744275SJD

8697442757115	Sterilization Gusset Reel 450 mm x 85 mm x 100 m, 60g 2 Indicators	869744275SJD
8697442757122	Sterilization Gusset Reel 500 mm x 85 mm x 100 m, 60g 2 Indicators	869744275SJD
8697442757139	Sterilization Flat Reel 450 mm x 200 m, 60g 3 Indicators	869744275SJD
8697442757146	Sterilization Flat Reel 500 mm x 200 m, 60g 3 Indicators	869744275SJD
8697442757153	Sterilization Gusset Reel 450 mm x 80 mm x 100 m, 60g 3 Indicators	869744275SJD
8697442757160	Sterilization Gusset Reel 500 mm x 80 mm x 100 m, 60g 3 Indicators	869744275SJD
8697442757177	Sterilization Flat Reel 450 mm x 200 m, 70g 2 Indicators	869744275SJD
8697442757184	Sterilization Flat Reel 500 mm x 200 m, 70g 2 Indicators	869744275SJD
8697442757191	Sterilization Gusset Reel 450 mm x 80 mm x 100 m, 70g 2 Indicators	869744275SJD
8697442757207	Sterilization Gusset Reel 500 mm x 80 mm x 100 m, 70g 2 Indicators	869744275SJD
8697442757214	Sterilization Flat Reel 450 mm x 200 m, 70g 3 Indicators	869744275SJD
8697442757221	Sterilization Flat Reel 500 mm x 200 m, 70g 3 Indicators	869744275SJD
8697442757238	Sterilization Gusset Reel 450 mm x 80 mm x 100 m, 70g 3 Indicators	869744275SJD
8697442757245	Sterilization Gusset Reel 500 mm x 80 mm x 100 m, 70g 3 Indicators	869744275SJD
8697442757283	Sterilization Reel Without Print 450 mm x 200 m	869744275SJD
8697442757290	Sterilization Reel Without Print 500 mm x 200 m	869744275SJD

### Additional Information:

Development, production and distribution are supported by a Quality Management System according to ISO 9001:2015 AND ISO 13485:2016 requirements. The Quality Management System has been certified by the notified body Royalcert (Certificate No: 00108/ DÖR09B and No: 00108/ DÖR13A). As proof of compliance of the products with the requirements of Council Directive 2017/745 on Medical devices, the products are considered Class I nonsterile products.

**Ankara Turkey**

**04.08.2021**

Canan ÖKTEM

General Manager



# SERTİFİKA

Sertifika No : 00108/DÖR09B  
Belgelendirme Tarihi : 20.01.2010  
Yeniden Belgelendirme Karar Tarihi : 07.01.2022  
Yayın Tarihi : 11.01.2023  
Geçerlilik Tarihi : 19.01.2024  
Revizyon Tarihi/No : 31.12.2018 / 01

Royalcert, aşağıda bilgileri verilen kuruluşun yönetim sisteminin değerlendirildiğini ve ilgili standardın gereklerine uygun olduğunu onaylar.

## ISO 9001:2015

### DÖRT-A TIP MALZEMELERİ SANAYİ İTH. İHR. TİC. LTD. ŞTİ.

Balıkhisar Mahallesi, Köy İçü Serpmeleri, No:795/A, Akyurt, Ankara, TÜRKİYE

**Scope:** Sterilizasyon Rulosu ve Torbaları, Kendinden Yapışkanlı Sterilizasyon Zarfları, Bowie-Dick Testi Paketleri, İndikatör Kartları (H2O2 (Plasma), Formaldehit İndikatör Kartları, Etilen Oksit İndikatör Kartları, Kuru Hava İndikatör Kartları, Sınıf 4 İndikatör Kartları, Sınıf 5 İndikatör Kartları, Sınıf 6 İndikatör Kartları), Sınıf 5 İntegratör, Rapid Buhar Biyolojik İndikatörü, Uzun Süreli Buhar Biyolojik İndikatörü, Etilen Oksit Biyolojik İndikatörü, H2O2 (Plasma) Biyolojik İndikatörü, Helix Küme Testi, Pcd Küme Testi, Etilen Oksit Yük Kontrol Testi, Otoklav Bantları (Buhar, Etilen Oksit, Plasma, Formaldehite), Koter Kalemleri, Koter Zımparası, Wrap ve Krep Kağıtları, Vücut-Yara Atık Sıvıları için Drenaj Sistemleri (Kateterler, Toplama Şişeleri), Polypropylene Mesh, Steril Konteynır Sistemleri, Konteynır Etiketleri, Konteynır Kilidi, Konteynır Filtresi, İndikatörlü Dokümantasyon Etiketleri, İndikatörlü Rulo Barkod Etiketleri; Yıkayıcı Dezenfektörler, Ultrasonik Cihazlar Ve Cerrahi Aletlerin Yıkama Kontrol Testleri (Protest, Hemotest, Washertest, Cannulacontrol Test, Sonicontrol Test), İkili Biyolojik İndikatör Test Paketi (Biyolojik İndikatör - Type 5 Entegratör), İkili Yük Kontrol Test Paketi ( Type 5 Entegratör ve PCD içi Type 6 İndikatör), Üçlü Biyolojik İndikatör Test Paketi (Biyolojik İndikatör, Type 5 Entegratör ve PCD içi Type 6 İndikatör), Üretimi, Tasarımı, Montajı, Paketlenmesi, Pazarlanması ve Satışı, Tek Kullanımlık Tıbbi Malzemelerin Paketlenmesi

Genel Müdür



Kalite Yönetim Sistemi  
TS EN ISO/IEC 17021  
AB-0014-YS



TÜRKAK BDS NO  
YS-A340-01E5



Bu sertifika, belgeli kuruluş gözetim denetimleri şartlarına ve RoyalCert'in prosedürlerine uyduğu sürece geçerlidir. Orjinal belgede hologram etiket bulunur. Belgelendirme periyodu 3 yıldır. Sertifikanın durumu [www.royalcert.com](http://www.royalcert.com) adresinden ayrıca üzerinde kare kod bulunan sertifikaların geçerliliği de TÜRKAK BDS no. ile [TBDS.turkak.org.tr](http://TBDS.turkak.org.tr) üzerinden doğrulanabilir.

RoyalCert Belgelendirme ve Gözetim A.Ş  
Kar Plaza E Blok K:13 34752  
Ataşehir, İstanbul  
T: +90 216 688 09 10





# CERTIFICATE

Certification No : 00108/DÖR09B  
Initial Certification Date : 20.01.2010  
Recertification Date : 07.01.2022  
Issue Date : 07.01.2022  
Expiration Date : 19.01.2024  
Revision Date / No : 31.12.2018 / 01

RoyalCert, certifies that the management system of the organization has been assessed and found to be in accordance with the requirements of the related standard.

## ISO 9001:2015

### DÖRT-A TIP MALZEMELERİ SANAYİ İTHALAT İHRACAT TİCARET LİMİTED ŞİRKETİ

Balıkhisar Mahallesi, Köy İçi Serpmeleri, No:795/A, Akyurt, Ankara, TURKEY

**Scope:** Production, Design, Assembly and Packaging of Sterilization Reels and bags, Self Adhesive Sterilization Pouches, 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, Rapid Steam Biological Indicator, Longtime Steam Biological Indicator, Ethylene Oxide Biological Indicator, H2O2 ( Plasma ) Biological Indicator, Helix Group Tests, PCD Group Tests, Ethylene Oxide Load Control test, Autoclave Tapes (Steam, Ethylene Oxide, Plasma, Formaldehyde), ESU Pencils, ESU Pencil Tip Cleaner, Wrap and Crepe Paper Sheets, Drainage Systems for Body-Wound Liquid Wastes (Catheters, Storage Bottles), Polypropylene Mesh, Sterile Container System, Container Label, Container Seal, Container Filter, Documentation Labels with Indicator, Reel Barcode Labels with Indicator, 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- Type 5 Integrator), Double Load Control Test Package (Type 5 Integrator and Inner PCD Type 6 Indicator), Triple Biological Indicator Test Package (Biological Indicator, Type 5 Integrator and Inner PCD Type 6 Indicator) and Packaging, of Disposable Medical Products

General Manager



TÜRKAK BDS NO  
YS-A340-01E5



This certification was conducted in accordance with the RoyalCert auditing and certification procedures and is subject to regular surveillance audits. The original certificate contains a security hologram. Certification period is 3 years Verifiable at: [www.royalcert.com](http://www.royalcert.com) This certification can be verified on TÜRKAK BDS no. and [TBDS.turkek.org.tr](http://TBDS.turkek.org.tr)

RoyalCert Belgelendirme ve Gözetim A.Ş.  
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# SERTİFİKA

Sertifika No	: 00108/DÖR13A
Belgelendirme Tarihi	: 20.01.2010
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Royalcert, aşağıda bilgileri verilen kuruluşun yönetim sisteminin değerlendirildiğini ve ilgili standardın gereklerine uygun olduğunu onaylar.

## ISO 13485:2016

### DÖRT-A TIP MALZEMELERİ SANAYİ İTH. İHR. TİC. LTD. ŞTİ.

Balikhisar Mahallesi, Köy İçi Serpmeleri, No:795/A, Akyurt, Ankara, TÜRKİYE

**Scope:** Sterilizasyon Rulosu ve Torbaları, Kendinden Yapışkanlı Sterilizasyon Zarfları, Bowie-Dick Testi Paketleri, İndikatör Kartları (H2O2 (Plasma), Formaldehit İndikatör Kartları, Etilen Oksit İndikatör Kartları, Kuru Hava İndikatör Kartları, Sınıf 4 İndikatör Kartları, Sınıf 5 İndikatör Kartları, Sınıf 6 İndikatör Kartları), Sınıf 5 İntegratör, Rapid Buhar Biyolojik İndikatörü, Uzun Süreli Buhar Biyolojik İndikatörü, Etilen Oksit Biyolojik İndikatörü, H2O2 (Plasma) Biyolojik İndikatörü, Helix Küme Testi, Pcd Küme Testi, Etilen Oksit Yük Kontrol Testi, Otoklav Bantları (Buhar, Etilen Oksit, Plasma, Formaldehite), Koter Kalemleri, Koter Zımparası, Wrap ve Krep Kağıtları, Vücut-Yara Atık Sıvıları için Drenaj Sistemleri (Kateterler, Toplama Şişeleri), Polypropylene Mesh, Steril Konteynir Sistemleri, Konteynir Etiketleri, Konteynir Kilidi, Konteynir Filtresi, İndikatörlü Dokümantasyon Etiketleri, İndikatörlü Rulo Barkod Etiketleri; Yıkayıcı Dezenfektörler, Ultrasonik Cihazlar Ve Cerrahi Aletlerin Yıkama Kontrol Testleri (Protest, Hemotest, Washertest, Cannulacontrol Test, Sonicontrol Test), İkili Biyolojik İndikatör Test Paketi (Biyolojik İndikatör - Type 5 Entegratör), İkili Yük Kontrol Test Paketi (Type 5 Entegratör ve PCD içi Type 6 İndikatör), Üçlü Biyolojik İndikatör Test Paketi (Biyolojik İndikatör, Type 5 Entegratör ve PCD içi Type 6 İndikatör), Üretimi, Tasarımı, Montajı, Paketlenmesi, Pazarlanması ve Satışı, Tek Kullanımlık Tıbbi Malzemelerin Paketlenmesi

Genel Müdür



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RoyalCert Belgelendirme ve Gözetim A.Ş.  
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# CERTIFICATE

Certification No : 00108/DÖR13A  
Initial Certification Date : 20.01.2010  
Recertification Date : 07.01.2022  
Issue Date : 07.01.2022  
Expiration Date : 19.01.2024  
Revision Date / No : 31.12.2018 / 01

RoyalCert, certifies that the management system of the organization has been assessed and found to be in accordance with the requirements of the related standard.

## ISO 13485:2016

**DÖRT-A TIP MALZEMELERİ SANAYİ İTH. İHR. TİC. LTD. ŞTİ.**

Balikhisar Mahallesi, Köy İçi Serpmeleri, No:795/A, Akyurt, Ankara, TURKEY

**Scope:** Production, Design, Assembly and Packaging of Sterilization Reels and bags, Self Adhesive Sterilization Pouches, 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, Rapid Steam Biological Indicator, Longtime Steam Biological Indicator, Ethylene Oxide Biological Indicator, H2O2 ( Plasma ) Biological Indicator, Helix Group Tests, PCD Group Tests, Ethylene Oxide Load Control test, Autoclave Tapes (Steam, Ethylene Oxide, Plasma, Formaldehyde), ESU Pencils, ESU Pencil Tip Cleaner, Wrap and Crepe Paper Sheets, Drainage Systems for Body-Wound Liquid Wastes (Catheters, Storage Bottles), Polypropylene Mesh, Sterile Container System, Container Label, Container Seal, Container Filter, Documentation Labels with Indicator, Reel Barcode Labels with Indicator, 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- Type 5 Integrator), Double Load Control Test Package (Type 5 Integrator and Inner PCD Type 6 Indicator), Triple Biological Indicator Test Package (Biological Indicator, Type 5 Integrator and Inner PCD Type 6 Indicator) and Packaging, of Disposable Medical Products

General Manager



This certification was conducted in accordance with the RoyalCert auditing and certification procedures and is subject to regular surveillance audits. The original certificate contains a security hologram. Certification period is 3 years Verifiable at: [www.royalcert.com](http://www.royalcert.com) This certification can be verified on TÜRKAK BDS no. and TBDS.turkak.org.tr

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## **GHID DE UTILIZARE ROLE DE STERILIZARE**

1. Rolele au 5, 7,5, 10, 15, 20, 25, 30, 35 și 40 cm (+/- 1 cm) lățime și 200 m lungime (+/- 1 mt)
2. Rolele sunt tăiate cu o porțiune de 5-7 cm de sus și de jos.
3. După procesul de tăiere, produsul este plasat în rolă.
4. Partea de sus și de jos va fi deschisă. Este închis cu o mașină adecvată de căldură și etanșare.
5. Dacă este necesar, indicatorul poate fi pus în rolă. După aceea, va fi gata pentru procesul de sterilizare.
6. Există 2 sau 3 indicatori pe partea laterală a rolelor. Indicatorii sunt pentru abur, oxid de etilenă și formaldehidă.
7. După procesul de sterilizare, culoarea se schimbă ca mai jos :

(STEAM) De la albastru la verde

(EO) de la roz la portocaliu

(FO) de la violet la verde

8. Procesul de sterilizare se face la :

134°C timp de 3,5 min sau 7 min

121°C timp de 15min

### **ATENȚIE**

- \* Vă rugăm să acordați atenție deformării și ruperii pachetelor.
- \* Nu supraîncărcați pachetele.
- \* Vă rugăm să acordați atenție rezistenței de etanșare a ambelor capete.
- \*Nu folosiți produse deteriorate
- \*Păstrați produsele la temperatura camerei 25°C

**TECHNICAL DATA SHEET**

**STERILIZATION FLAT/GUSSET REEL, 60gsm**

<b>TECHNICAL DATA SHEET</b>	<b>PRODUCT CODE</b>	:	<b>4AFR (Flat Reel) - 4AGR (Gusset Reel)</b>		
	<b>RELATED STANDARDS</b>	:	4A Medical flat and gusseted reels are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the reel production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. 4A Medical Reels meet the requirements of 93/42/EEC Medical Device Directive regulations		
	<b>INTENDED USE</b>	:	4A Medical reels are designed to provide excellent barrier for sterile medical device packaging purposes. Reels meet the Medical Industry's requirement for high quality, hygiene and safety levels. 4A Medical reels are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization. 4A Medical reels are ease to package and indicator used for the sterilization provides information with the sterilization status of the medical devices. Sterilized material in sterilization package is storable for up to 5 years after the sterilization in a clean room conditions.		
	<b>FILLING VOLUME</b>	:	According to DIN 58953-7 (German national standard): Sealeable paper bags and sealeable pouches and reels shall be filled up to 3/4 max of their volume. This limits avoids too high stress / burdon to the seals. Below the bottom seal there must be space of minimum 30 mm between load and sealing area. There is no known limit bu standarts for weight and it is based on experience. However, it is suggested to follow the 3/4 rule. In terms of solid, heavy load (metal instruments), it is the weight itself, in case of any sharp objects which could damage the material, and the volume of condensate (directly related to mass=weight) which is created during the steam sterilization.		
	<b>OPERATION CONDITIONS</b>	:	4A Medical reels are used for steam, ethylene oxide, formaldehyde sterilization methods. The sterilization conditions should be determined by the end user regarding to material to be sterilized.		
	<b>SPECIFICATIONS</b>	:			
<b>MEDICAL PAPER</b>	<b>PROPERTIES</b>		<b>UNITS</b>	<b>STANDARD</b>	<b>TYPICAL VALUE</b>
	SUBSTANCE		g/m <sup>2</sup>	ISO 536	60,0
	THICKNESS		µm	ISO 534	76
	BENDTSEN POROSITY		ml/min	ISO 5636-3	650
	AIR PERMEANCE		µm (Pa*s)	ISO 5636-3	7,4
	BENDTSEN ROUGHNESS FS		ml/min	ISO 8791-2	250
	BENDTSEN ROUGHNESS WS		ml/min	ISO 8791-2	250
	PORE SIZE		µm	EN 868-2 (app.D)	17
	TENSILE STRENGTH, MD		kN/m	EN ISO 1924-2	5,9
	TENSILE STRENGTH, CD		kN/m	EN ISO 1924-2	2,9
	WET TENSILE STRENGTH, MD		kN/m	ISO 3781	1,6
	WET TENSILE STRENGTH, CD		kN/m	ISO 3781	0,9
	BURST STRENGHT		kPa	ISO 2758	300
	WET BURST		kPa	ISO 3689	100
	TEARING STRENGHT MD		mN	ISO 1974	600
	TEARING STRENGHT CD		mN	ISO 1974	650
	COBB TEST (60s)		g/m <sup>2</sup>	ISO 535	15,0
	WATER REPELLENCY		s	EN 868-2 (app.E)	30,0
	FLOUORESCENCE		pts/dm <sup>2</sup>	EN 868-2 (app.B)	0,0
FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS					

## TECHNICAL DATA SHEET

### STERILIZATION FLAT/GUSSET REEL, 60gsm

TECHNICAL DATA SHEET

LAMINATED FILM	PROPERTIES	UNIT	TYPICAL VALUE	
	THICKNESS	Micron	LAM.FILM	52 ± 5
			PE	40 ± 5
			PET	12 ± 2
BREAKING FACTOR	N/15mm	35		
TEAR STRENGTH MD/CD	mN	300		
BOND STRENGHT	N/m	265		
ELONGATION	%	70		
TEMPERATURE DURABILITY	min/degrees	30 min/140C		
FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				

**PRODUCT SPECIFICATION :**

POUCH	PROPERTIES	UNIT	TYPICAL VALUE
	SEAL STRENGTH	N/15mm	2,5
	BUBBLE TEST		None
	PINHOLE DETERMINATION		None
	DIMENSION CONTROL	cm or mm	Desired dimensions
	LEAKAGE TEST		None
	PEEL DIRECTION		None
	INDICATOR CONTROL		Returns the specified color

INDICATOR	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
	STEAM	BLUE	GREEN
	EO	PINK	ORANGE
	FORMALDEHYDE	PURPLE	GREEN
<b>PACKAGING:</b>		4A Medical reels are packaged in carton boxes as below: Flat Reels are 200m long and Gusset Reels are 100m long.	

Product dimensions	Pieces in carton
50mm X 200m /	10
75mm X 200m / 75mm X 100m	8
100mm X 200m / 100mm X 100m	8
120mm X 200m / 120mm X 100m	4
150mm X 200m / 150mm X 100m	4
200mm X 200m / 200mm X 100m	4
250mm X 200m / 250mm X 100m	2
300mm X 200m / 300mm X 100m	2
350mm X 200m / 350mm X 100m	2
400mm X 200m / 400mm X 100m	2
420mm X 200m / 420mm X 100m	2
450mm X 200m / 450mm X 100m	2
500mm X 200m / 500mm X 100m	2

**MANUFACTURER :** **DORT-A TIP MALZEMELERİ SAN. İTH. İHR. TIC. LTD. STİ.**  
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