



## Certificate Of Compliance

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

BALIKHISAR MAHALLESİ, KÖY İÇİ SERPMELERİ, NO: 795/A, AKYURT, ANKARA, TÜRKİYE

Certex Certification confirms that the above-mentioned organization has evaluated the Medical Devices Management System and that it complies with the requirements of the relevant standard.

## ISO 13485:2016

### Scope,

Production, Design, Assembly and Packaging of Sterilization Reels (Flat, Gusset, Tyvek and Reinforced) and Pouches (Flat, Gusset, Tyvek, Self Sealing, Reinforced Flat, Reinforced Self Sealing, Gamma), Header Bag, Bowie-Dick Test Packages (200 Sheet, 400 Sheet, 200 Sheet Wrapped With Crepe Paper, 400 Sheet Wrapped With Crepe Paper, With Box, Wrapped With Crepe Paper & EWS) A4 Bowie-Dick, Mini Bowie Dick, Indicator Strips ( H2O2 Plasma 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 Biological Indicators (Steam, Ethylene Oxide, H2O2 ( Plasma ) ), Longtime Biological Indicators (Steam, Ethylene Oxide, H2O2 ( Plasma ) ), Helix Load Control Tests, PCD Load Control Tests, Ethylene Oxide Load Control Test, Autoclave Tapes (Steam, Ethylene Oxide, Plasma, Formaldehyde, Dry Heat), ESU Pencils, ESU Pencil Tip Cleaner, Wrap and Crepe Paper Sheets, Drainage Systems for Body-Wound Liquids (Catheters, Bottles/Reservoirs), Polypropylene Mesh, Label Gun, Steam and Ethylene Oxide Marker, Incubator, Steam and Ethylene Oxide Dot Sticker, Sterile Container Systems and Accessories, Container Label, Container Seal, Container Filter, Documentation Labels with Indicator (Steam, Ethylene Oxide, H2O2 ( Plasma ), Dry Heat), Instrument Protector, Reel Barcode Labels with Indicator, Washer Disinfectors, Washing Control Tests of Ultrasonic Devices and Surgical Instruments (Pro Test, Hemo Tests, Washer Test, Washer Test with Glass, PLS Cannula Control Test, Sonicontrol Test ), Aluminum Sonicontrol Test and Aluminum Washer Test, Plastic Washer Test, Plastic Sonicontrol Test, Double Biological Indicator Test Package (Biological Indicator- Type 5 Integrator), Double Load Control Test Package (Type 5 integrator and Inner PCDIndicator), Triple Biological indicator Test Package (Biological Indicator, Type 5 Integrator and Inner PCD Type 6 Indicators) and Packaging, of Disposable Medical Products

*This certificate is based on compliance with Certex Certification rules and annual surveillance audits are successfully completed, the date of the first publication valid for a period of three years. The validity of the certificate is subject to an annual depends on the surveillance audit. Certificate validity status It can be checked at [www.certex.com.tr](http://www.certex.com.tr).*

Certificate No : CER-TC-0040  
Certificate Initial Issue Date : 13.01.2025  
Certificate Issue Date : 13.01.2025  
Certificate Validity Date : 12.01.2026

Certex Certification Training and Surveillance Services Ltd. Co.  
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**Dört-A Tıp Malzemeleri  
Sanayi İth. İhr. Tic. Ltd. Şti.**

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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 Medical Device Regulation 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. We declare that this declaration is prepared under our responsibility as manufacturer.

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

**Company SRN No:** TR-MF-000019642

**ADDRESS:** Balıkhisar Mah. Köy İçerisinde No:795/A AKYURT/ ANKARA / TÜRKİYE

**Products:** Sterilization Reels and Pouches (Flat, Gusset, Tyvek, Reinforced), Self Sealing Sterilization Pouches

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

**Rule:** Rule-I - 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/ Medical Device Regulation	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>	<b>Product Code</b>
8680829700262	Sterilization Flat Reel 450 mm x 200 m, 60g 3Indicators	868082970SG3	4AFR450200/60/3
8681176422531	Sterilization Flat Reel 500 mm x 200 m, 60g 3Indicators	86811764SW2	4AFR500200/60/3
8681176421084	Tyvek Sterilization Reel 75 mm x 100 m	86811764SW2	4ATR75100
8681176421091	Tyvek Sterilization Reel 100 mm x 100 m	86811764SW2	4ATR100100
8681176421107	Tyvek Sterilization Reel 120 mm x 100 m	86811764SW2	4ATR120100
8681176421114	Tyvek Sterilization Reel 150 mm x 100 m	86811764SW2	4ATR150100
8681176421121	Tyvek Sterilization Reel 200 mm x 100 m	86811764SW2	4ATR200100
8681176421138	Tyvek Sterilization Reel 250 mm x 100 m	86811764SW2	4ATR250100
8681176421145	Tyvek Sterilization Reel 300 mm x 100 m	86811764SW2	4ATR300100
8681176421152	Tyvek Sterilization Reel 350 mm x 100 m	86811764SW2	4ATR350100
8681176421169	Tyvek Sterilization Reel 400 mm x 100 m	86811764SW2	4ATR400100
8681176421176	Tyvek Sterilization Reel 450 mm x 100 m	86811764SW2	4ATR450100
8681176421183	Tyvek Sterilization Reel 500 mm x 100 m	86811764SW2	4ATR500100

8697442750222	Sterilization Flat Reel 50 mm x 200 m, 60g 3Indicators	869744275SJD	4AFR50200/60/3
8697442750239	Sterilization Flat Reel 75 mm x 200 m, 60g 3Indicators	869744275SJD	4AFR75200/60/3
8697442750246	Sterilization Flat Reel 100 mm x 200 m, 60g 3Indicators	869744275SJD	4AFR100200/60/3
8697442750253	Sterilization Flat Reel 120 mm x 200 m, 60g 3Indicators	869744275SJD	4AFR120200/60/3
8697442750260	Sterilization Flat Reel 150 mm x 200 m, 60g 3 Indicators	869744275SJD	4AFR150200/60/3
8697442750277	Sterilization Flat Reel 200 mm x 200 m, 60g 3 Indicators	869744275SJD	4AFR200200/60/3
8697442750284	Sterilization Flat Reel 250 mm x 200 m, 60g 3 Indicators	869744275SJD	4AFR250200/60/3
8697442750291	Sterilization Flat Reel 300 mm x 200 m, 60g 3 Indicators	869744275SJD	4AFR300200/60/3
8697442750307	Sterilization Flat Reel 350 mm x 200 m, 60g 3 Indicators	869744275SJD	4AFR350200/60/3
8697442750314	Sterilization Flat Reel 400 mm x 200 m, 60g 3 Indicators	869744275SJD	4AFR400200/60/3
8697442750338	Sterilization Gusset Reel 75 mm x 45 mm x 100 m, 60g 3 Indicators	869744275SJD	4AGR75100/60/3
8697442750345	Sterilization Gusset Reel 100 mm x 50 mm x 100m, 60g 3 Indicators	869744275SJD	4AGR100100/60/3
8697442750369	Sterilization Gusset Reel 150 mm x 55 mm x 100m, 60g 3 Indicators	869744275SJD	4AGR150100/60/3
8697442750376	Sterilization Gusset Reel 200 mm x 60 mm x 100m, 60g 3 Indicators	869744275SJD	4AGR200100/60/3
8697442750383	Sterilization Gusset Reel 250 mm x 65 mm x 100m, 60g 3 Indicators	869744275SJD	4AGR250100/60/3
8697442750390	Sterilization Gusset Reel 300 mm x 70 mm x 100m, 60g 3 Indicators	869744275SJD	4AGR300100/60/3
8697442750406	Sterilization Gusset Reel 350 mm x 75 mm x 100m, 60g 3 Indicators	869744275SJD	4AGR350100/60/3
8697442750413	Sterilization Gusset Reel 400 mm x 80 mm x 100 m, 60g 3 Indicators	869744275SJD	4AGR400100/60/3

8697442750642	Sterilization Flat Reel 50 mm x 200 m, 70g 3Indicators	869744275SJD	4AFR50200/70/3
8697442750659	Sterilization Flat Reel 75 mm x 200 m, 70g 3 Indicators	869744275SJD	4AFR75200/70/3
8697442750666	Sterilization Flat Reel 100 mm x 200 m, 70g 3 Indicators	869744275SJD	4AFR100200/70/3
8697442750673	Sterilization Flat Reel 120 mm x 200 m, 70g 3Indicators	869744275SJD	4AFR120200/70/3
8697442750680	Sterilization Flat Reel 150 mm x 200 m, 70g 3Indicators	869744275SJD	4AFR150200/70/3
8697442750697	Sterilization Flat Reel 200 mm x 200 m, 70g 3Indicators	869744275SJD	4AFR200200/70/3
8697442750703	Sterilization Flat Reel 250 mm x 200 m, 70g 3 Indicators	869744275SJD	4AFR250200/70/3
8697442750710	Sterilization Flat Reel 300 mm x 200 m, 70g 3Indicators	869744275SJD	4AFR300200/70/3
8697442750727	Sterilization Flat Reel 350 mm x 200 m, 70g 3Indicators	869744275SJD	4AFR350200/70/3
8697442750734	Sterilization Flat Reel 400 mm x 200 m, 70g 3 Indicators	869744275SJD	4AFR400200/70/3
8697442750758	Sterilization Gusset Reel 75 mm x 45 mm x 100m, 70g 3 Indicators	869744275SJD	4AGR75100/70/3
8697442750765	Sterilization Gusset Reel 100 mm x 50 mm x 100 m, 70g 3 Indicators	869744275SJD	4AGR100100/70/3
8697442750789	Sterilization Gusset Reel 150 mm x 55 mm x 100 m, 70g 3 Indicators	869744275SJD	4AGR150100/70/3
8697442750796	Sterilization Gusset Reel 200 mm x60 mm x 100 m, 70g 3 Ind.	869744275SJD	4AGR200100/70/3
8697442750802	Sterilization Gusset Reel 250 mm x 65 mm x 100m, 70g 3 Indicators	869744275SJD	4AGR250100/70/3
8697442750819	Sterilization Gusset Reel 300 mm x 70 mm x 100m, 70g 3 Indicators	869744275SJD	4AGR300100/70/3
8697442750826	Sterilization Gusset Reel 350 mm x 75 mm x 100m, 70g 3 Indicators	869744275SJD	4AGR350100/70/3
8697442750833	Sterilization Gusset Reel 400 mm x 80 mm x 100m, 70g 3 Indicators	869744275SJD	4AGR400100/70/3
8697442750949	Tyvek Sterilization Reel 500 mm x 70 m	869744275SJD	4ATR50070
8697442754978	Tyvek Sterilization Reel 75 mm x 70 m	869744275SJD	4ATR7570
8697442754985	Tyvek Sterilization Reel 100 mm x 70 m	869744275SJD	4ATR10070
8697442755005	Tyvek Sterilization Reel 150 mm x 70 m	869744275SJD	4ATR15070
8697442755012	Tyvek Sterilization Reel 200 mm x 70 m	869744275SJD	4ATR20070
8697442755029	Tyvek Sterilization Reel 250 mm x 70 m	869744275SJD	4ATR25070
8697442755036	Tyvek Sterilization Reel 300 mm x 70 m	869744275SJD	4ATR30070
8697442755043	Tyvek Sterilization Reel 350 mm x 70 m	869744275SJD	4ATR35070
8697442755050	Tyvek Sterilization Reel 400 mm x 70 m	869744275SJD	4ATR40070
8697442755715	Tyvek Sterilization Reel 120 mm x 70 m	869744275SJD	4ATR12070
8697442757153	Sterilization Gusset Reel 450 mm x 80 mm x 100m, 60g 3 Indicators	869744275SJD	4AGR450100/60/3
8697442757160	Sterilization Gusset Reel 500 mm x 80 mm x 100m, 60g 3 Indicators	869744275SJD	4AGR500100/60/3
8697442757214	Sterilization Flat Reel 450 mm x 200 m, 70g 3 Indicators	869744275SJD	4AFR450200/70/3

8697442757221	Sterilization Flat Reel 500 mm x 200 m, 70g 3 Indicators	869744275SJD	4AFR500200/70/3
8697442757238	Sterilization Gusset Reel 450 mm x 80 mm x 100m, 70g 3 Indicators	869744275SJD	4AGR450100/70/3
8697442755685	Tyvek Sterilization Reel 50 mm x 70 m	869744275SJD	4ATR5070
8681176425020	Tyvek Sterilization Reel 50 mm x 100 m	86811764SW2	4ATR50100
8681176424801	Tyvek Sterilization Reel 450 mm x 70 m	86811764SW2	4ATR45070
8697442757245	Sterilization Gusset Reel 500 mm x 80 mm x 100m, 70g 3 Indicators	869744275SJD	4AGR500100/70/3
8681176424931	Sterilization Self Sealing Pouch 90 mm x 160 mm 60g 3 Indicators	86811764SW2	4ASSP90160/60/3
8681176424948	Sterilization Self Sealing Pouch 90 mm x 260 mm 60g 3 Indicators	86811764SW2	4ASSP90260/60/3
8681176424955	Sterilization Self Sealing Pouch 100 mm x 200 mm 60g 3 Indicators	86811764SW2	4ASSP100200/60/3
8681176424467	Sterilization Self Sealing Pouch 130 mm x 290 mm 60g 3 Indicators	86811764SW2	4ASSP130290/60/3
8681176424962	Sterilization Self Sealing Pouch 135 mm x 260 mm 60g 3 Indicators	86811764SW2	4ASSP135260/60/3
8681176424979	Sterilization Self Sealing Pouch 140 mm x 295 mm 60g 3 Indicators	86811764SW2	4ASSP140295/60/3
8681176424986	Sterilization Self Sealing Pouch 150 mm x 270 mm 60g 3 Indicators	86811764SW2	4ASSP150270/60/3
8681176424993	Sterilization Self Sealing Pouch 190 mm x 360 mm 60g 3 Indicators	86811764SW2	4ASSP190360/60/3
8681176424108	Sterilization Reinforced Reel 50 mm x 100 m 60g 3 Indicators	86811764SW2	4ARFR50100/60/3
8681176424115	Sterilization Reinforced Reel 75 mm x 100 m 60g 3 Indicators	86811764SW2	4ARFR75100/60/3
8681176424122	Sterilization Reinforced Reel 100 mm x 100 m 60g 3 Indicators	86811764SW2	4ARFR100100/60/3
8681176424139	Sterilization Reinforced Reel 150 mm x 100 m 60g 3 Indicators	86811764SW2	4ARFR150100/60/3
8681176424146	Sterilization Reinforced Reel 200 mm x 100 m 60g 3 Indicators	86811764SW2	4ARFR200100/60/3
8681176424153	Sterilization Reinforced Reel 250 mm x 100 m 60g 3 Indicators	86811764SW2	4ARFR250100/60/3
8681176424160	Sterilization Reinforced Reel 300 mm x 100 m 60g 3 Indicators	86811764SW2	4ARFR300100/60/3
8681176424177	Sterilization Reinforced Reel 350 mm x 100 m 60g 3 Indicators	86811764SW2	4ARFR350100/60/3
8681176424184	Sterilization Reinforced Reel 400 mm x 100 m 60g 3 Indicators	86811764SW2	4ARFR400100/60/3
8681176424191	Sterilization Reinforced Reel 450 mm x 100 m 60g 3 Indicators	86811764SW2	4ARFR450100/60/3
8681176424207	Sterilization Reinforced Reel 500 mm x 100 m 60g 3 Indicators	86811764SW2	4ARFR500100/60/3
8681176425006	Sterilization Self Sealing Pouch 200 mm x 350 mm 60g 3 Indicators	86811764SW2	4ASSP200350/60/3

8681176425013	Sterilization Self Sealing Pouch 300 mm x 390mm 60g 3 Indicators	86811764SW2	4ASSP300390/60/3
8681176424481	Sterilization Self Sealing Pouch 300 mm x 400mm 60g 3 Indicators	86811764SW2	4ASSP300400/60/3
8681176425556	Sterilization Flat Pouch 50 mm x 200 mm 60g 3 Indicators	86811764SW2	4AFP50200/60/3
8681176425563	Sterilization Flat Pouch 75 mm x 250 mm 60g 3 Indicators	86811764SW2	4AFP75250/60/3
8681176425570	Sterilization Flat Pouch 100 mm x 250 mm 60g 3 Indicators	86811764SW2	4AFP100250/60/3
8681176425587	Sterilization Flat Pouch 100 mm x 300 mm 60g 3 Indicators	86811764SW2	4AFP100300/60/3
8681176425594	Sterilization Flat Pouch 100 mm x 400 mm 60g 3 Indicators	86811764SW2	4AFP100400/60/3
8681176425600	Sterilization Flat Pouch 125 mm x 250 mm 60g 3 Indicators	86811764SW2	4AFP125250/60/3
8681176425617	Sterilization Flat Pouch 125 mm x 400 mm 60g 3 Indicators	86811764SW2	4AFP125400/60/3
8681176425624	Sterilization Gusset Pouch 100 mm x 50 mm x 200 mm 60g 3 Indicators	86811764SW2	4AGP100200/60/3
8681176425631	Sterilization Gusset Pouch 150 mm x 55 mm x 300 mm 60g 3 Indicators	86811764SW2	4AGP150300/60/3
8681176425648	Sterilization Gusset Pouch 150 mm x 55 mm x 450 mm 60g 3 Indicators	86811764SW2	4AGP150450/60/3
8681176425655	Sterilization Gusset Pouch 200 mm x 60 mm x 300 mm 60g 3 Indicators	86811764SW2	4AGP200300/60/3
8681176425662	Sterilization Gusset Pouch 200 mm x 60 mm x 390 mm 60g 3 Indicators	86811764SW2	4AGP200390/60/3
8681176425679	Sterilization Gusset Pouch 200 mm x 60 mm x 450 mm 60g 3 Indicators	86811764SW2	4AGP200450/60/3
8681176425686	Sterilization Gusset Pouch 250 mm x 65 mm x 450 mm 60g 3 Indicators	86811764SW2	4AGP250450/60/3
8681176425693	Sterilization Gusset Pouch 250 mm x 65 mm x 550 mm 60g 3 Indicators	86811764SW2	4AGP250550/60/3
8681176425709	Sterilization Self Sealing Pouch 60 mm x 140 mm 60g 3 Indicators	86811764SW2	4ASSP60140/60/3
8681176425716	Sterilization Self Sealing Pouch 70 mm x 200 mm 60g 3 Indicators	86811764SW2	4ASSP70200/60/3
8681176425723	Sterilization Self Sealing Pouch 90 mm x 140 mm 60g 3 Indicators	86811764SW2	4ASSP90140/60/3
8681176425730	Sterilization Self Sealing Pouch 90 mm x 200 mm 60g 3 Indicators	86811764SW2	4ASSP90200/60/3
8681176425747	Sterilization Self Sealing Pouch 100 mm x 250 mm 60g 3 Indicators	86811764SW2	4ASSP100250/60/3
8681176425754	Sterilization Self Sealing Pouch 100 mm x 360 mm 60g 3 Indicators	86811764SW2	4ASSP100360/60/3
8681176425761	Sterilization Self Sealing Pouch 130 mm x 300 mm 60g 3 Indicators	86811764SW2	4ASSP130300/60/3
8681176425778	Sterilization Self Sealing Pouch 140 mm x 410 mm 60g 3 Indicators	86811764SW2	4ASSP140410/60/3

8681176425785	Tyvek Sterilization Pouch 125 mm x 175 mm	86811764SW2	4ATP125175
8681176425792	Tyvek Sterilization Pouch 150 mm x 200 mm	86811764SW2	4ATP150200
8681176425808	Tyvek Sterilization Pouch 200 mm x 250 mm	86811764SW2	4ATP200250
8681176425815	Tyvek Sterilization Pouch 200 mm x 300 mm	86811764SW2	4ATP200300
8681176425822	Crepe Paper, 60g 300 mm x 300 mm	86811764SW2	4ACP300300
8681176425839	Crepe Paper, 60g 350 mm x 350 mm	86811764SW2	4ACP350350
8681176425846	Crepe Paper, 60g 400 mm x 400 mm	86811764SW2	4ACP400400
8681176425853	Crepe Paper, 60g 500 mm x 500 mm	86811764SW2	4ACP500500
8681176425860	Crepe Paper, 60g 600 mm x 600 mm	86811764SW2	4ACP600600
8681176425877	Crepe Paper, 60g 750 mm x 750 mm	86811764SW2	4ACP750750
8681176425884	Crepe Paper, 60g 900 mm x 900 mm	86811764SW2	4ACP900900
8681176425891	Crepe Paper, 60g 1000 mm x 1000 mm	86811764SW2	4ACP100100
8681176425907	Crepe Paper, 60g 1200 mm x 1200 mm	86811764SW2	4ACP12001200
8681176425914	SMS Paper, 43g 300 mm x 300 mm	86811764SW2	4ASMS300300/43
8681176425921	SMS Paper, 43g 400 mm x 400 mm	86811764SW2	4ASMS400400/43
8681176425938	SMS Paper, 43g 500 mm x 500 mm	86811764SW2	4ASMS500500/43
8681176425945	SMS Paper, 43g 600 mm x 600 mm	86811764SW2	4ASMS600600/43
8681176425952	SMS Paper, 43g 750 mm x 750 mm	86811764SW2	4ASMS750750/43
8681176425969	SMS Paper, 43g 900 mm x 900 mm	86811764SW2	4ASMS900900/43
8681176425976	SMS Paper, 43g 1000 mm x 1000 mm	86811764SW2	4ASMS10001000/43
8681176425983	SMS Paper, 43g 1200 mm x 1200 mm	86811764SW2	4ASMS12001200/43
8681176425990	SMS Paper, 60g 300 mm x 300 mm	86811764SW2	4ASMS300300/60
8681176426003	SMS Paper, 60g 400 mm x 400 mm	86811764SW2	4ASMS400400/60
8681176426010	SMS Paper, 60g 500 mm x 500 mm	86811764SW2	4ASMS500500/60
8681176426027	SMS Paper, 60g 600 mm x 600 mm	86811764SW2	4ASMS600600/60
8681176426034	SMS Paper, 60g 750 mm x 750 mm	86811764SW2	4ASMS750750/60
8681176426041	SMS Paper, 60g 900 mm x 900 mm	86811764SW2	4ASMS900900/60
8681176426058	SMS Paper, 60g 1000 mm x 1000 mm	86811764SW2	4ASMS10001000/60
8681176426065	SMS Paper, 60g 1200 mm x 1200 mm	86811764SW2	4ASMS12001200/60



## **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 and Certex Certification (Certificate No: 108 / DOR09B and CER-TC-0040) As proof of compliance of the products with the requirements of Medical Device Regulation 2017/745 on Medical devices, the products are considered Class I nonsterile products.

**Ankara Turkey**

16.01.2025

Canan ÖKTEM

General Manager

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