

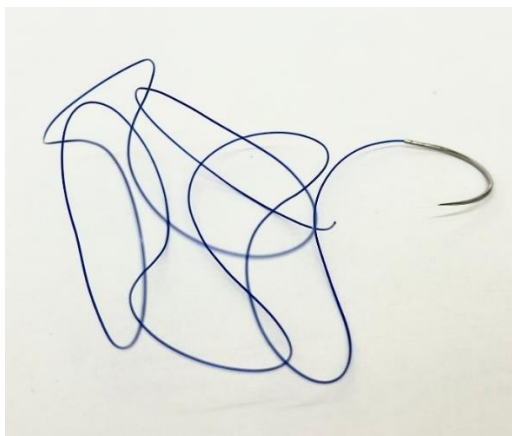
	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

1.Product Information

1.1 General Product Name:

Sterile, Single Use, Non Absorbable, Synthetic, Monofilament, Polypropylene Surgical Suture

1.2 Product Images



Product codes and Description:

ORIGINAL PRODUCT BARCODE	CODE DESCRIPTION	PRODUCT REFERENCE CODE	BRAND NAME	GMDN CODE	CLASS	SHELF LIFE (MONTHES)
8681677072662	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLUE) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE02K40	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070422	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLUE) 45mm 3/8 CIRCLE NORMAL CUTTING NEEDLE	DE02KD45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009649	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLUE) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DE02M40	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070934	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE0K30	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8681677070521	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE0K36	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070989	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE0K40	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070064	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 25mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	DE0KDN25	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070514	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DE0M30	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070897	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 36mm 1/2 CIRCLE TAPER POINT NEEDLE	DE0M36	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009625	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DE0M40	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677074697	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 0 (BLUE) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DE0M40-100	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070439	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLUE) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE1K36	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677071009	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLUE) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE1K40	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070330	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLUE) 36mm 1/2 CIRCLE TAPER POINT NEEDLE	DE1M36	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8681665009632	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLUE) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DE1M40	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677072167	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 1 (BLUE) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DE1M40-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009663	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE2K26	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677072105	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE2K30	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009656	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 22mm 3/8 CIRCLE NORMAL CUTTING NEEDLE	DE2KD22	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677073874	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 2-0 (BLUE) 22mm 3/8 CIRCLE NORMAL CUTTING NEEDLE	DE2KD22-150	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070385	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 25mm 1/2 CIRCLE TAPER POINT NEEDLE	DE2M25	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009670	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DE2M26	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677072099	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DE2M30	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677072242	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 60mm STRAIGHT REVERSE CUTTING NEEDLE	DE2SK60	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8681677072082	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE3K19	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677073461	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE3K20	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009687	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE3K26	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070095	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 3-0 (BLUE) 17mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE3M17-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009700	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DE3M20	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677072068	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DE3M22	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070200	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DE3M26	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009694	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 3-0 (BLUE) 26mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE3M26-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677072075	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DE3M30	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677074062	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 60mm STRAIGHT REVERSE CUTTING NEEDLE	DE3SK60	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8681677070903	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE4K16	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677071023	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE4K20	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677075670	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE4K26	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009731	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 16mm 3/8 CIRCLE NORMAL CUTTING NEEDLE	DE4KD16	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009724	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 13mm 1/2 CIRCLE TAPER POINT NEEDLE	DE4M13	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009717	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 4-0 (BLUE) 13mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE4M13-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009748	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 16mm 1/2 CIRCLE TAPER POINT NEEDLE	DE4M16	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070026	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 4-0 (BLUE) 16mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE4M16-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070392	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DE4M17	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070163	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 4-0 (BLUE) 17mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE4M17-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8681677070910	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DE4M20	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070248	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 20mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE4M20-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070170	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 4-0 (BLUE) 20mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE4M20-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009755	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DE4M26	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070187	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 4-0 (BLUE) 26mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE4M26-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070750	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 13mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE5K13	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009786	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE5K16	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070323	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 13mm 1/2 CIRCLE TAPER POINT NEEDLE	DE5M13	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009762	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 13mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE5M13-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677072051	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 16mm 1/2 CIRCLE TAPER POINT NEEDLE	DE5M16	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8681677071016	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 16mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE5M16-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070552	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DE5M17	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681665009779	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 17mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE5M17-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070255	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 10mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE6K10	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070415	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 13mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE6K13	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677075694	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 13mm 3/8 CIRCLE REVERSE CUTTING DOUBLE NEEDLE	DE6K13-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070958	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE6K16	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677075700	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 11mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE6M11-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677070767	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 13mm 1/2 CIRCLE TAPER POINT NEEDLE	DE6M13	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677072044	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 13mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE6M13-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8681677075847	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 18mm 1/2 CIRCLE TAPER POINT NEEDLE	DE4M18	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677075885	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 35mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE0K35	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677076172	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 1 (BLUE) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DE1M40-100	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677076189	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DE2M20	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677076196	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE2K20	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677076202	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 16mm 1/2 CIRCLE TAPER POINT NEEDLE	DE6M16	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677076240	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLUE) 37mm 1/2 CIRCLE TAPER POINT NEEDLE	DE1M37	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677076585	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLUE) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE1K30	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677076608	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLUE) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DE1M30	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677076615	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 3-0 (BLUE) 20mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE3M20-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8681677077070	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLUE) 45mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE1K45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077063	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 35mm 1/2 CIRCLE TAPER POINT NEEDLE	DE0M35	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077100	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLUE) 45mm 1/2 CIRCLE TAPER POINT NEEDLE	DE1M45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077087	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 10mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE6M10-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077094	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 10mm 3/8 CIRCLE REVERSE CUTTING DOUBLE NEEDLE	DE6K10-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077117	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLUE) 45mm 1/2 CIRCLE TAPER POINT NEEDLE	DE02M45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077124	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLUE) 45mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE02K45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077131	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE3K30	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077186	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE4K19	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077193	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 24mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE3K24	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8681677077209	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE2K36	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077414	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (BLUE) 30mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE2M30-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077421	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 3-0 (BLUE) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DE3M26-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077445	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE5K19	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077773	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 16mm 3/8 CIRCLE REVERSE CUTTING DOUBLE NEEDLE	DE5K16-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077841	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (BLUE) 55mm STRAIGHT REVERSE CUTTING NEEDLE	DE2SK55-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677077889	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 26mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE3M26-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078046	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 6-0 (BLUE) 17mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE6K17-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078053	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 4-0 (BLUE) 22mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE4K22-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078091	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (BLUE) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DE2M26-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8681677078060	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (BLUE) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DE2M30-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078077	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 1 (BLUE) 45mm 1/2 CIRCLE TAPER POINT NEEDLE	DE1M45-100	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078107	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 0 (BLUE) 45mm 1/2 CIRCLE TAPER POINT NEEDLE	DE0M45-100	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078084	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 5-0 (BLUE) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE5K19-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078138	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLUE) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DE1M26	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078145	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DE0M26	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078398	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE3DS18	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078404	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 17mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE4DS17	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078411	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 17mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE5DS17	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078473	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 24mm 1/2 CIRCLE TAPER CUT NEEDLE	DE2HSY24	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8681677078459	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 27mm 1/2 CIRCLE TAPER POINT NEEDLE	DE4HR27	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078466	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 60mm STRAIGHT NORMAL CUTTING NEEDLE	DE2GC60	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078480	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 24mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DE2HS24	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677078695	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 24mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE2DS24	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677079081	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 17mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE4HR17-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677079456	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 22mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE40DS22	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677079463	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 23mm 1/2 CIRCLE TAPER POINT NEEDLE	DE30HR23	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677079470	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 23mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE30DS23	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677079487	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DE40HR22	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677079579	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 5-0 (BLUE) 15mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE50DS15-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8681677079586	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 5-0 (BLUE) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE50DS16-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677079722	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 20mm 3/8 CIRCLE TAPER POINT DOUBLE NEEDLE	DE40DR20-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677079739	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 5-0 (BLUE) 17mm 3/8 CIRCLE TAPER POINT DOUBLE NEEDLE	DE50DR17-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677079746	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 6-0 (BLUE) 13mm 3/8 CIRCLE TAPER POINT DOUBLE NEEDLE	DE60DR13-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677079753	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (BLUE) 17mm 1/2 CIRCLE TAPER CUT DOUBLE NEEDLE	DE20HRT17-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677079760	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (BLUE) 26mm 1/2 CIRCLE TAPER CUT DOUBLE NEEDLE	DE20HRT26-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677079777	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 5-0 (BLUE) 16mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE50HR16-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677079784	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 60cm USP SIZE 6-0 (BLUE) 13mm 3/8 CIRCLE TAPER POINT DOUBLE NEEDLE	DE60DR13-D-60	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8681677079791	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 60cm USP SIZE 2-0 (BLUE) 13mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE60HR13-D-60	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154200138	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (BLUE) 26mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE2M26-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8684154200596	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE DYED) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE40DS16	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154200602	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE DYED) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE40DS19	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154200619	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 17mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DE40HS17	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154200626	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 20mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DE40HS20	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154200633	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 18mm 1/2 CIRCLE TAPER CUT NEEDLE	DE40HRT18	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154200640	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE DYED) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DE40HR17	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154200657	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE DYED) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DE40HR20	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154200770	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 4-0 (BLUE) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE40DS16-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154200848	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE40DS18	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154200855	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE50DS18	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8684154200862	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE50DS20	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154201029	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 6-0 (BLUE) 16mm 3/8 CIRCLE NORMAL CUTTING NEEDLE	DE60DC16-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154201074	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 6-0 (BLUE) 12mm 3/8 CIRCLE TAPER CUT NEEDLE	DE60DRT12-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154201654	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 0 (BLUE) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE00DS40-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154201661	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (BLUE) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DE01HR40-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154201678	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (BLUE) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE20DS30-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154201685	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 3-0 (BLUE) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE30DS26-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154201715	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 24mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE40DS24	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154201722	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE60DS19	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154201777	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (BLUE) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE01DS40-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8684154201784	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 0 (BLUE) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DE00HR40-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154201821	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 0 (BLUE) 36mm 1/2 CIRCLE NORMAL CUTTING EDGE DOUBLE NEEDLE	DE00HC36-D- 100	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154202378	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 24mm 1/2 CIRCLE TAPER POINT NEEDLE	DE30HR24	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154202385	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 0 (BLUE) 40mm 1/2 CIRCLE TAPER POINT NEEDLE (LOOPED ON)	DE00HR40-L-150	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154202460	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 10mm 1/2 CIRCLE TAPER POINT NEEDLE	DE60HR10	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154202477	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 60cm USP SIZE 7-0 (BLUE) 10mm 3/8 CIRCLE TAPER POINT DOUBLE NEEDLE	DE70DR10-D-60	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154202484	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 12mm 3/8 CIRCLE REVERSE CUTTING DOUBLE NEEDLE	DE50DS12-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154202491	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 16mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DE40HS16	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154202507	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 3-0 (BLUE) 25mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE30HR25-D- 100	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154202514	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 40mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	DE00HC40	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8684154202521	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLUE) 40mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	DE01HC40	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154202866	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 18mm 1/2 CIRCLE TAPER POINT NEEDLE	DE50HR18	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154202873	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 18mm 1/2 CIRCLE TAPER POINT NEEDLE	DE60HR18	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154203313	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 1 (BLUE) 40mm 1/2 CIRCLE TAPER POINT NEEDLE (LOOPED ON)	DE01HR40-L-150	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154203382	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DE30HR17	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154203399	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 17mm 3/8 CIRCLE TAPER POINT DOUBLE NEEDLE	DE50DR17-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154203405	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 12mm 3/8 CIRCLE TAPER POINT DOUBLE NEEDLE	DE60DR12-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154203412	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 0 (BLUE) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DE00HR30-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154203429	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 6-0 (BLUE) 10mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE60HR10-D-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154203450	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (BLUE) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE20DS26-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8684154203467	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 4-0 (BLUE) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DE40HR20-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154203474	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 4-0 (BLUE) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE40DS20-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154203511	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 12mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE50DS12	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154203528	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 5-0 (BLUE) 20mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE50HR20-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154203535	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 5-0 (BLUE) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DE50HR17-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154204235	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLUE) 40mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DE01HS40	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154204242	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 40mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DE00HS40	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154204303	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 0 (BLUE) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DE00HR26-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154204310	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 18mm 1/2 CIRCLE TAPER POINT NEEDLE	DE30HR18	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154204327	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 30mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DE00HS30	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8684154204334	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLUE) 30mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DE01HS30	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154204341	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLUE) 30mm 3/8 CIRCLE TAPER POINT NEEDLE	DE02DR30	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154205966	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 0 (BLUE) 36mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	DE00HC36-100	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154206093	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 10mm 1/2 CIRCLE TAPER POINT NEEDLE	DE50HR10	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154206109	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 22mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE30DS22	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154206383	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 2-0 (BLUE) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE20DS26-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154206390	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 3-0 (BLUE) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE30DS26-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154206406	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 4-0 (BLUE) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE40DS19-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154206758	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 24mm 1/2 CIRCLE TAPER POINT NEEDLE	DE20HR24	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154206765	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 12mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE60DS12	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8684154206772	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 12mm 1/2 CIRCLE TAPER POINT NEEDLE	DE60HR12	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154206918	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (BLUE) 35mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE20DS35-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154206949	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 13mm 3/8 CIRCLE TAPER POINT NEEDLE	DE60DR13	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154206956	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 7-0 (BLUE) 10mm 3/8 CIRCLE TAPER POINT NEEDLE	DE70DR10	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154206963	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 7-0 (BLUE) 10mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE70DS10	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154207243	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 13mm 3/8 CIRCLE TAPER POINT DOUBLE NEEDLE	DE60DR13-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154207564	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 31mm 1/2 CIRCLE TAPER POINT NEEDLE	DE00HR31	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154207571	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 26mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE00HR26-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154207588	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 26mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE20HR26-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154207847	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLUE) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE00DS26	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8684154207854	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 7-0 (BLUE) 8mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE70DS8-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154207861	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 7-0 (BLUE) 10mm 3/8 CIRCLE TAPER POINT DOUBLE NEEDLE	DE70DR10-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154207878	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 60cm USP SIZE 8-0 (BLUE) 6.4mm 3/8 CIRCLE TAPER POINT DOUBLE NEEDLE	DE80DR6.4-D-60	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154207885	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 60cm USP SIZE 8-0 (BLUE) 8mm 3/8 CIRCLE TAPER POINT DOUBLE NEEDLE	DE80DR8-D-60	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154207892	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 60cm USP SIZE 9-0 (BLUE) 5mm 3/8 CIRCLE TAPER POINT NEEDLE	DE90DR5-60	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154208042	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 36mm 1/2 CIRCLE TAPER POINT NEEDLE	DE20HR36	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154208059	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 19mm 1/2 CIRCLE TAPER POINT NEEDLE	DE50HR19	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154208417	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (BLUE) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DE01HR30-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154208424	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (BLUE) 20mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE20HR20-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154208479	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 30mm 3/8 CIRCLE TAPER POINT NEEDLE	DE20DR30	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8684154208486	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 22mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DE20HS22	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154208608	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 3-0 (BLUE) 25mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DE30DS25-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154208615	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 3-0 (BLUE) 25mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DE30HR25-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154208622	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 3-0 (BLUE) 17mm 1/2 CIRCLE TAPER CUT DOUBLE NEEDLE	DE30HRT17-D-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154208660	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (BLUE) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DE20HR40-90	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154208677	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 0 (BLUE) WITHOUT NEEDLE	DE00-1X150	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154208684	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 1 (BLUE) WITHOUT NEEDLE	DE01-1X150	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154208691	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLUE) 10mm 3/8 CIRCLE TAPER POINT NEEDLE	DE60DR10	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154208929	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 60mm STRAIGHT NORMAL CUTTING DOUBLE NEEDLE	DE20GC60-D	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
8684154208936	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 8-0 (BLUE) 8mm 1/2 CIRCLE TAPER POINT NEEDLE	DE80HR8	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

8684154208943	DAMALENE: PP MONOFILAMENT NON- ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 8-0 (BLUE) 8mm 1/2 CIRCLE TAPER POINT NEEDLE	DE80HR8-45	DAMALENE	13909 - Suture, polypropylene MONOFILAMENT	Class III	60
---------------	---	------------	----------	---	-----------	----

1.3 Gmdn Code

13909- Suture, polypropylene monofilament. DESCRIPTION: It is a sterile thread made of polypropylene monofilament, which is used to suture the edges of a wound or incision together. CATEGORIES: 03-Dental devices 10-Disposable devices

1.4 Intended use of the product:

Surgical sutures are sterile threads that are attached to needle and are used for surgical procedures.

DAMALENE, POLYPROPYLENE sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, plastic and neurological procedures.

DAMALENE blue colour sterile, synthetic, monofilament, polypropylene, nonabsorbable sutures are not subject to degradation or weakening by tissue enzymes. They are extremely inert in tissue and have been found to retain tensile strength for periods of as long as two years in vivo. Polypropylene sutures cause minimal tissue reaction and hold knots better than most other synthetic monofilament materials.

1.5 Patient Populations

The patients are used for all people who are need to ligate, close and cover suturable wounds under sterile conditions by initially suturing the wound due to cardiovascular, gastrointestinal, obstetric and gynecologic, urologic and ophthalmic surgery.

1.6 Intended User

The device should used by physician and/or surgeons.

1.7 Repeat Applications, Including Any Restrictions as to the Number or Duration of Reapplications

After surgery, the closing and covering can be repeated if an undesirable case would be occurred and/or the wound would open. There is not any restriction as to the number or duration of reapplications.

Single Use / Reusable

The device is only single-used.

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

1.8 Mechanism of Action

DAMALENE sutures elicit minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. Polypropylene monofilament surgical suture is not absorbed, nor is any significant change in tensile strength retention known to occur in vivo.

DAMALENE, POLYPROPYLENE is available in a range of gauge sizes and lengths, non-needle or attached to stainless steel needles of varying types and sizes.

The product range of SUTURE varies as the diameter of sterile non absorbable surgical suture strands from 0,050 mm to 0,599 mm. The length of sterile non absorbable surgical suture strands varies from 45 cm to 180 cm. The length of needles varies from 8 mm to 60 mm. The shape of needles varies from 3/8 to 1/2 circle or straight. The different variants are listed in the PRODUCT LIST of DAMALENE, POLYPROPYLENE

DAMALENE, POLYPROPYLENE and sutures elicits minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. Polypropylene monofilament surgical suture is not absorbed, nor is any significant change in tensile strength retention known to occur in vivo.

Surgical suture is a medical device used to hold body tissues together after an injury or surgery.

It is used for closing and covering suturable wounds under sterile conditions by initially suturing and stapling the wound.

*According to the size of the strands that meets all the requirements of the European Pharmacopoeia (EP) for Synthetic Non-Absorbable Multifilament Sutures and the requirements of United States Pharmacopoeia (USP) Non-Absorbable Sutures except for a slight oversize in diameter

1.9 Components and Raw Materials of product: Surgical Suture Surgical Needle

Manufacturer/Supplier	Material
G. Krahmer GmbH	Polypropylene Uncoating Blue
Quality Needles Pvt Co.	Stainless Steel 300 (Serial number)
FTM Ambalaj	Second packing (medical paper)
Endustri Matbaacılık	Paper (slat)

1.10 . Accessories Information

There is no accessories.

1.11 Suitability of Raw Material

Raw materials are supplied from the suppliers given in 1.4. Components of

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

product. Raw materials analysis reports are given in Test Reports

1.12 Indication, Contraindication and Adverse Reactions

1.12.1. Indications:

DAMALENE, POLYPROPYLENE sutures are indicated for use in Gastrointestinal Surgery, obstetric and gynecologic surgery and urological surgery, soft tissue approximation and/or ligation, including ophthalmic procedures.

*** Damalene sutures are indicated for use in cardiovascular surgery.**

1.12.2. Contraindications:

DAMALENE, POLYPROPYLENE, being not absorbable should not be used where extended approximation of tissue under stress is required. There are not known any other contraindications of DAMALENE, POLYPROPYLENE polypropylene monofilament sutures.

1.12.3. Adverse Reactions

Adverse effects associated with the use of this device include wound dehiscence, failure to provide wound support in closure of the abdomen, chest, joints, and other sites where expansion, stretching or distension occur. Failure to provide adequate wound support in elderly, malnourished or debilitated patients, or in patients suffering from cancer, anemia, obesity, diabetes, infected or other conditions which may delay wound healing, enhance bacterial infectivity, minimal acute inflammatory tissue reaction, localized irritation when skin closures are left in place for greater than seven days, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions, such as urine and bile occurs, and pain, edema and at the wound site.

*One package unit of DAMALENE, POLYPROPYLENE contains 12 single pouches.

1.13 Material Specifications:

The following components and compounds are used for the manufacturing of the surgical sutures:

1.13.1 Thread

(Polypropylene, non absorbable, monofilament, blue colour) The following specifications are met:

Appearance:

The polypropylene non-absorbable suture is composed of synthetic monofilament materials for the intended size to meet current USP specifications. The polypropylene has been dyed blue.

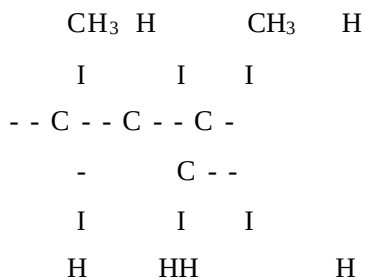
Blue colored for easy identification during Surgery.

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

Name:

Polypropylene

Formula of polypropylene polimer



Additives:

The quantity of colour additive is not to exceed 0.5 % by weight of the suture.

Dyestuffs

Blue coloured threads

Chemical name: Phthalocyaninato (-2)) copper in accordance with FDA requirements

Reference: Federal Register, title 21, 74.3045

Coating

Uncoated

Physical Specification

DAMALENE, POLYPROPYLENE braids meet all requirements established by the United States Pharmacopoeia (USP) and the European Pharmacopoeia (EP) except for diameter.

The diameter could be slightly over the specification.

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

Suture Biological Physical Properties : Polypropylene

EP SIZE	USP SIZE	DIA METER			Knot pull tensile strength		Suture-Needle tensile strength	
		A Dia meter average (mm)	B Min values (mm)	Max values (mm)	C Average values kgf (N)	D Min values kgf (N)	A Average (kgf) (N)	B Min values (kgf) (N)
0.3	9-0	0.030-0.039	0.025	0.045	0.035	0.006	0.021	0.015
0.4	8-0	0.040-0.049	0.035	0.060	0.060	0.015	0.05	0.025
0.5	7-0	0.050-0.069	0.045	0.085	0.10	0.035	0.08	0.04
0.7	6-0	0.070-0.099	0.060	0.125	0.15	0.060	0.17	0.08
1	5-0	0.100-0.149	0.085	0.175	0.30	0.100	0.23	0.11
1.5	4-0	0.150-0.199	0.125	0.225	0.50	0.150	0.45	0.23
2	3-0	0.200-0.249	0.175	0.275	0.90	0.300	0.68	0.34
2.5	-	0.250-0.299	0.225	0.325	1.30	0.500	0.92	0.46
3	2-0	0.300-0.349	0.275	0.375	1.50	0.900	1.10	0.45
3.5	0	0.350-0.399	0.325	0.450	2.20	1.300	1.50	0.45
4	1	0.400-0.499	0.375	0.550	2.70	1.500	1.80	0.60
5	2	0.500-0.599	0.450	0.650	3.50	2.200	1.80	0.70
6	3	0.600-0.699	0.550	0.750	5.00	2.700	1.80	0.70
7	4	0.700-0.799	0.650	0.850	6.20	3.500	1.80	0.70

Knot pull tensile strength linear pull tensile strength for non-sterile braid USP 29 NF24 Page 2050

USP Size	Metric Size (gauge no.)	Limits on Average Diameter (mm)		Limits on Average Knot-Pull (except where otherwise specified) ^a Tensile Strength (in kgf) ^b			Limits on Average Knot-Pull (except where otherwise specified) ^a Tensile Strength (in N) ^b		
		Min.	Max.	Class I Min.	Class II Min.	Class III Min.	Class I Min.	Class II Min.	Class III Min.
12-0	0.01	0.001	0.009	0.001 ^a	—	0.002 ^a	0.01 ^a	—	0.02 ^a
11-0	0.1	0.010	0.019	0.006 ^a	0.005 ^a	0.02 ^a	0.06 ^a	0.05 ^a	0.20 ^a
10-0	0.2	0.020	0.029	0.019 ^a	0.014 ^a	0.06 ^a	0.194 ^a	0.14 ^a	0.59 ^a
9-0	0.3	0.030	0.039	0.043 ^a	0.029 ^a	0.07 ^a	0.424 ^a	0.28 ^a	0.68 ^a
8-0	0.4	0.040	0.049	0.06	0.04	0.11	0.59	0.39	1.08
7-0	0.5	0.050	0.069	0.11	0.06	0.16	1.08	0.59	1.57
6-0	0.7	0.070	0.099	0.20	0.11	0.27	1.96	1.08	2.65
5-0	1	0.10	0.149	0.40	0.23	0.54	3.92	2.26	5.30
4-0	1.5	0.15	0.199	0.60	0.46	0.82	5.88	4.51	8.04
3-0	2	0.20	0.249	0.96	0.66	1.36	9.41	6.47	13.3
2-0	3	0.30	0.339	1.44	1.02	1.80	14.1	10.0	17.6
0	3.5	0.35	0.399	2.16	1.45	3.40 ^a	21.2	14.2	33.3 ^a
1	4	0.40	0.499	2.72	1.81	4.76 ^a	26.7	17.8	46.7 ^a
2	5	0.50	0.599	3.52	2.54	5.90 ^a	34.5	24.9	57.8 ^a
3 and 4	6	0.60	0.699	4.88	3.68	9.11 ^a	47.8	36.1	89.3 ^a
5	7	0.70	0.799	6.16	—	11.4 ^a	60.4	—	112 ^a
6	8	0.80	0.899	7.28	—	13.6 ^a	71.4	—	133 ^a
7	9	0.90	0.999	9.04	—	15.9 ^a	88.6	—	156 ^a
8	10	1.00	1.099	—	—	18.2 ^a	—	—	178 ^a
9	11	1.100	1.199	—	—	20.5 ^a	—	—	201 ^a
10	12	1.200	1.299	—	—	22.8 ^a	—	—	224 ^a

^a The tensile strength of sizes smaller than USP size 8-0 (metric size 0.4) is measured by straight pull. The tensile strength of sizes larger than USP size 2-0 (metric size 3) of monofilament Class III (metallic) Nonabsorbable Surgical Suture is measured by straight pull.

Silver wire meets the tensile strength values of Class I Sutures but is tested in the same manner as Class III Sutures.

^b The limits on knot-pull tensile strength apply to Nonabsorbable Surgical Suture that has been sterilized. For nonsterile Sutures of Class I and Class II, the limits are 25% higher.

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

Table 1. Standard Needle Attachment for Absorbable and Nonabsorbable Sutures

Metric Size (Gauge No.)		Limits on Needle Attachment					
Absorbable Collagen Suture	Nonabsorbable and Synthetic Absorbable Sutures	USP Size	Average (in kgf) (Min.)	Individual (in kgf) (Min.)	Average (in N) (Min.)	Individual (in N) (Min.)	
	0.1	11-0	0.007	0.005	0.069	0.049	
	0.2	10-0	0.014	0.010	0.137	0.098	
0.4	0.3	9-0	0.021	0.015	0.206	0.147	
0.5	0.4	8-0	0.050	0.025	0.490	0.245	
0.7	0.5	7-0	0.080	0.040	0.784	0.392	
1	0.7	6-0	0.17	0.08	1.67	0.784	
1.5	1	5-0	0.23	0.11	2.25	1.08	
2	1.5	4-0	0.45	0.23	4.41	2.25	
3	2	3-0	0.68	0.34	6.67	3.33	
3.5	3	2-0	1.10	0.45	10.8	4.41	
4	3.5	0	1.50	0.45	14.7	4.41	
5	4	1	1.80	0.60	17.6	5.88	
6 and larger	5 and larger	2 and larger	1.80	0.70	17.6	6.86	

Retention ratio of tensile strength

Polypropylene monofilament surgical suture is not absorbed, nor is any significant change in tensile strength retention known to occur in vivo.

1.13.2. NEEDLE:

Needle material is made from stainless steel and meets the internationally accepted specifications of surgically used metals.

For Analysis Certificates see Test Reports

1.13.3 Tipping solution Araldite Standart

Araldite Standart is a low visocisty cyanoacrylate adhesive for assembling medical devices. It is used to harden the tip of the suture in order to enable an easier suture insertion into the needle. The section that contains the adhesive does not remain in the body.

Araldite Standart offers the most comprehensive line of adhesives and sealants available to the medical device industry. These USP class VI and/or ISO-10993 compliant products are designed specifically for the assembly of medical devices where toxicity testing and sterilization resistance are required.

For Analysis Certificates see Test Reports

1.13.4 Specification of packaging material

packaging material is made from a pouch made of medical paper For

Analysis Certificates see Test Reports

1.14 Biological and Toxicological Evaluation

The following section contains information on the preclinical evaluation of the raw materials and the toxicological and biocompatibility tests on the sterile finished product DAMALENE, POLYPROPYLENE (Clinical and Biological Evaluation).

1.11. Biocompatibility Tests of the Raw Materials for Medical Device

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

(ISO10993-1:2009)

Specific safety evaluation programs follow International Organization for Standardization (ISO) 10993 standards and Food and Drug Administration (FDA) guidance (May 1, 1995). The table below is based on ISO 10993-1 Evaluation and testing, 2009 edition. The crosses (X) indicate data endpoints that can be necessary for a biological safety evaluation per ISO 10993-1, based on a risk analysis. Where existing data are adequate, additional testing is not required. (Clinical and Biological Evaluation)

Biocompatibility Test Matrix

DEVICE CATEGORIES			BIOLOGICAL EFFECT												
				Cytotoxicity	Sensitization	Irritation/Intracutaneous	Acute	Systemic Toxicity	Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	Reproductive/Developmental
SURFACE DEVICES	Skin	A	x	x	x										
		B	x	x	x										
		C	x	x	x										
	Mucosal Membrane	A	x	x	x										
		B	x	x	x										
		C	x	x	x		x	x							
	Breached or Compromised Surfaces	A	x	x	x										
		B	x	x	x										
		C	x	x	x		x	x							
EXTERNALLY COMMUNICATING DEVICES	Blood Path, Indirect	A	x	x	x	x					x				
		B	x	x	x	x					x				
		C	x	x		x	x	x		x					
	Tissue/Bone/Dentin Communicating	A	x	x	x										
		B	x	x	x	x	x	x	x						
		C	x	x	x	x	x	x	x						
	Circulating Blood	A	x	x	x	x					x				
		B	x	x	x	x	x	x	x	x					
		C	x	x	x	x	x	x	x	x					
IMPLANT DEVICES	Tissue/Bone	A	x	x	x										
		B	x	x	x	x	x	x	x						
		C	x	x	x	x	x	x	x						
	Blood	A	x	x	x	x	x			x	x				
		B	x	x	x	x	x	x	x	x					
		C	x	x	x	x	x	x	x	x					

In compliance with the standard EN ISO 10993-1, Table 1, the biocompatibility classification of our product and the tests required in accordance are determined as below:

The results of the biocompatibility tests on Sterile, Single Use, Non Absorbable, Synthetic, Monofilament, Polypropylene Surgical suture demonstrate the excellent biocompatibility of the material and also demonstrate that the ETO sterilization does not have any negative effects on the material

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

Based on the clinical experiences with the product DAMALENE, POLYPROPYLENE, the material documentation as well as the biocompatibility test results on the end product, the material used for the manufacturing of the surgical suture and the final product STERİLEN can be regarded as biocompatible and suitable for a clinical application.

1.12. Biodegradation for Medical Device DAMALENE, POLYPROPYLENE

Sterile, Single Use, Non-Absorbable, Synthetic, Monofilament, Polypropylene Surgical Suture

is not absorbed, progressive degradation in vivo may result in gradual loss of the sutures tensile strength over time.

1.13. Manufacturing Process:

Manufacturing is performed at the İkitelli OSB, İsdök Sosyal Tesis 2 sk. B Blok 1 B 7 Başakşehir/İstanbul, Turkey. The manufacturing is made under clean room conditions. The productions consist of manual insertion of the thread into the needles. After testing products are winded in a paper, then packed in a medical paper and the products are ETO sterilized in-house.

The following major manufacturing steps are used:

Manufacturing Methods

- Threads are applied with tipping solution
- Threads are cut to the required length.
- Threads are manually attached to needles using purpose made attaching machines in ISO 8 Clean Room.

Packaging Procedures

- After attaching, the suture is reverse wound into a retaining pouch leaving the needle accessible for easy withdrawal of the thread.
- The wound sutures are packed in a medical pouch envelope and labeled in ISO 8 Clean Room.

One package unit of DAMALENE, POLYPROPYLENE contains 12 single pouches.

Sterilization

DAMALENE, POLYPROPYLENE sutures are sterilized in-house by EtO. They are then vacuum-dried, sealed and packed.

Sterilization process is verified by chemical indicators and biological indicators are also used routinely to challenge the procedure. The sterilization process is validated according to EN ISO 11135-1:2014. Main routine sterilization parameters are 55 °C %30 Humidity with a gas injection period of 6 hours.

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

As regards the manufacturing / assembly area, environmental conditions are monitored at regular intervals using standard microbiological methods (i.e. culture plates)

Packaging into cartons

Twelve sutures pouches are packed into a carton and labelled. Each carton is cellophane wrapped. Hundred cartons are packed in a shipper, which is sealed. Each shipper is allocated a unique sequential identification number and labelled with the contents and their batch numbers.

Production Hygiene:

Production (Assembly) is performed under ISO 8 clean room conditions. Bioburden is checked on a routinely basis and controlled by responsible persons.

ETO-Residual Tests

ISO 10993-7:2008 provides limits for sterilization residuals based on product application.

ETO residuals are tested according to the requirements of ISO 10993-7:2008 by using gas chromatography.

EN 10993-7 Article 4.3.3 Prolonged exposure devices

The average daily dose of EO to patient shall not exceed 2 mg/d. In addition, the maximum EO dose shall not exceed:

– 4 mg in the first 24 h;

– 60 mg in the first 30 d.

The residual test is carried out according to EN 10993-7 and the results are shown in.

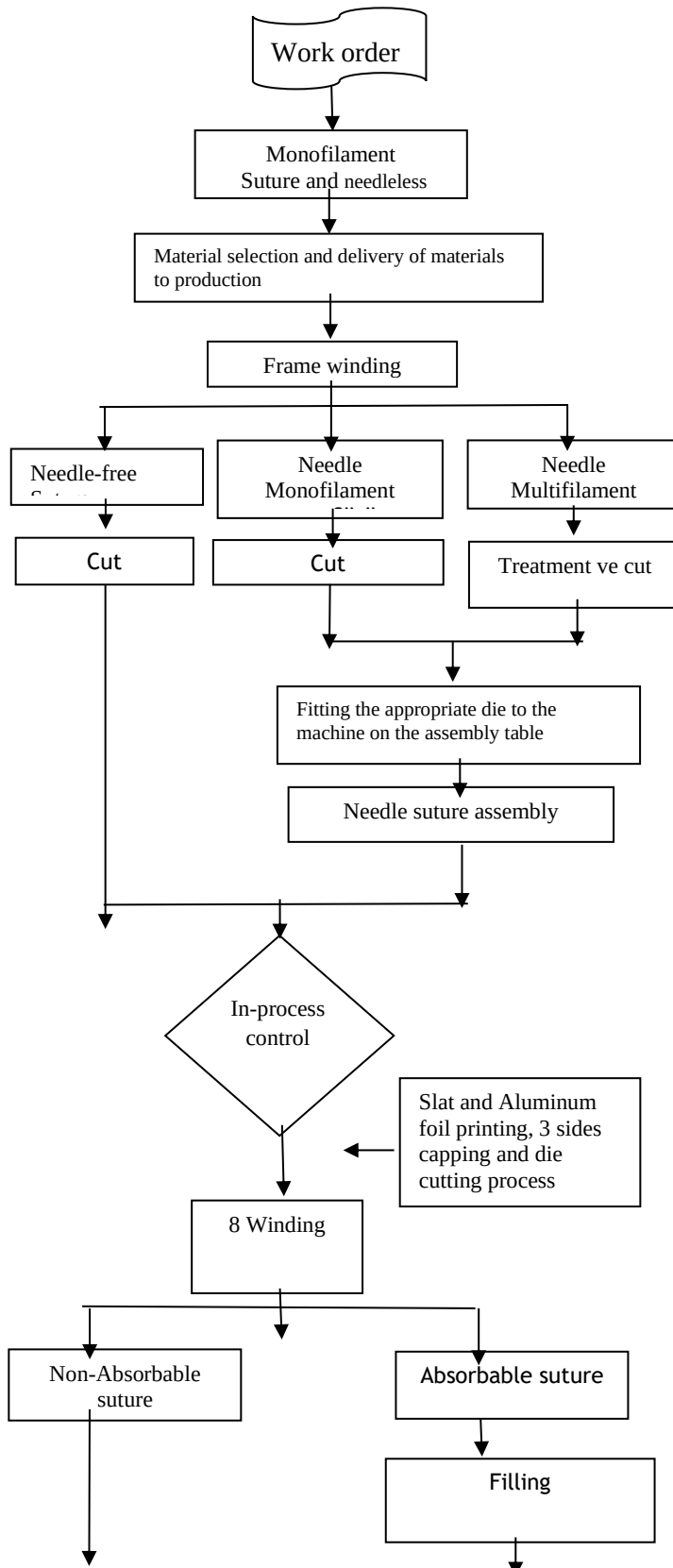
	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

Manufacturing Flow Chart

WORKFLOW

RELATED DOCUMENT

RESPONSIBLE



UR02001- Work Order Opening Instruction

UR02002-Work Order Compliant Material Selection Instruction

DP02007-Material to the warehouse Material Introduction and Production Exit Instruction

UR02003-Pulley Winding, Cutting and Machine Operation Instruction

UR02006-Installing Die Pull-Tester Adjustment Instruction

KG02021-In-Process Control Instruction

UR02007- Needle and Suture Installation Instruction

KG02021-In-process Control Instruction

KG02002-Suture Length Control and The Separation of the Needle from the Thread Strength Test

UR02014_inner winding cardboard, Aluminum Foil Preparation and Labeling Instruction

UR02009-Winding of sutures Inner winding carton on the table Instruction on hugging

Production

Production Supervisor

Store and shipping supervisor

Production Supervisor and Production Person

Production Supervisor

QA Manager

Production person

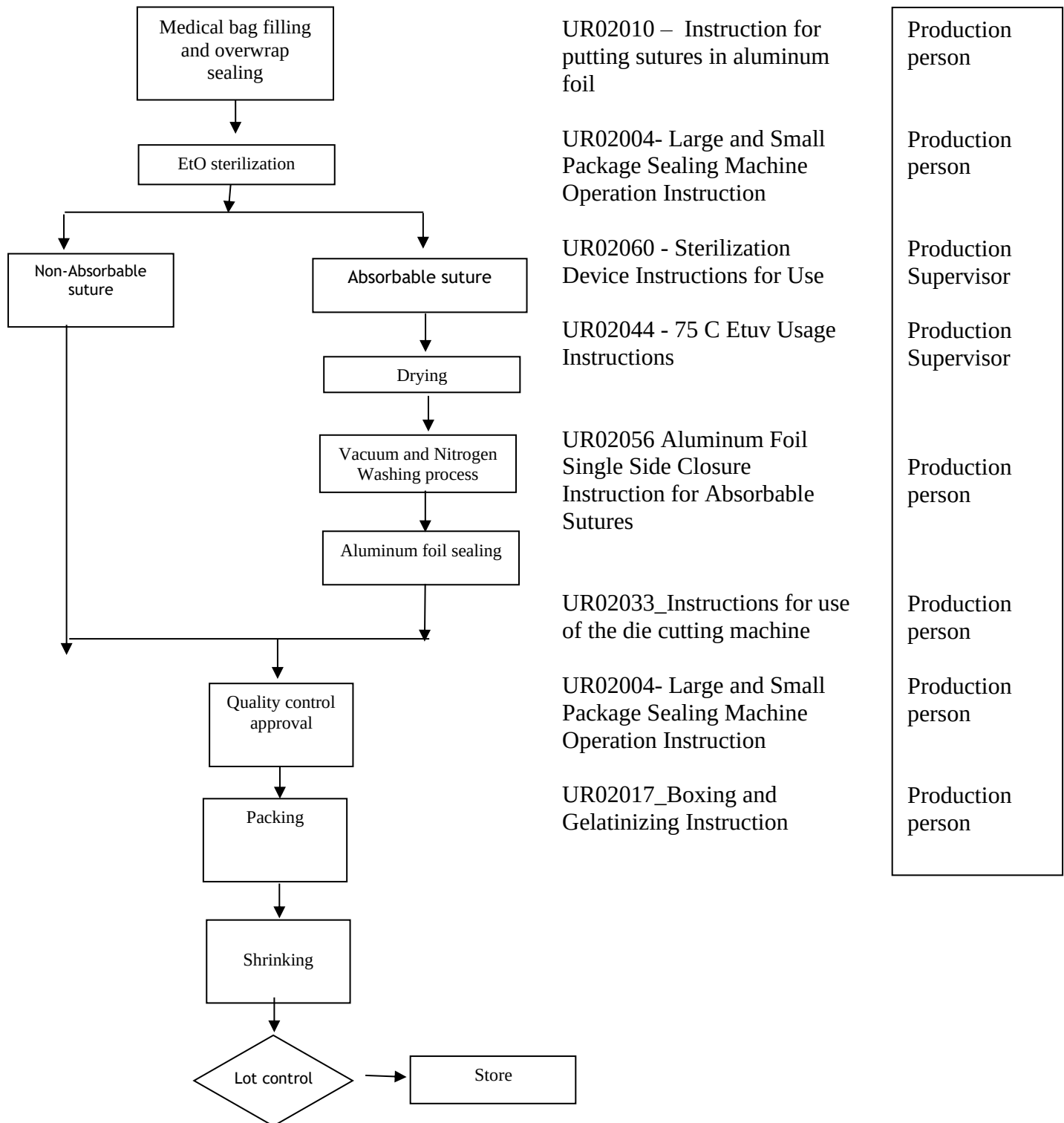
QA Manager

QA Manager

Production personnel

Production personnel

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023



From material entrance into the production to Temporary warehouse (carrantina area) all processes are carried out in GMD Clean room

1.14. Product and Test Specifications:

The DAMALENE, POLYPROPYLENE range of sutures started to successfully produced and extensively used in 2016.

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

The following tests are specified as final batch release controls according to USP 29: Table: Test specifications and Lot results.

Test Parameter	Method	Lot: 23E04E027		Lot: 23E05E027	
		Code: DE3K26		Code: DE3K26	
		Limit	result	limit	result
Needle Attachment	USP 25	6,8	14,9	6,8	15,8
Sterility Test	USP 25	sterile	sterile	sterile	sterile

The test reports of DAMALENE, POLYPROPYLENE lots given on the above table are given on test reports.

1.15. Stability/Aging Test and Product Life Time :

Stability Testing were performed as accelerated tests and real time tests according to ICH Guideline CPMP QWP 556/96

The product's shelf life was identified as 5 years according to the test results.

1.16. Product Tests (Performance):

The relevant tests and reports are given on Test Reports

1.17. The Product Classification

DAMALENE, POLYPROPYLENE According to annex IX, rule no. 8 of EC-Directive 93/42/EEC the product category DAMALENE, POLYPROPYLENE is classified as Medical Devices class IIb. The product is a non-absorbable medical device (surgical suture) for surgically invasive long-term implantation applications.

Rule 8:

“All implantable devices and long-term surgically invasive devices are in **Class IIb** unless they are intended:

- to be placed in the teeth, in which case they are in Class IIa,
- to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III,
- to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III,
- or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

According to annex IX, rule no. 8 of EC-Directive 93/42/EEC the product category is classified as Medical Devices **class III**. The product is a non-absorbable medical device (surgical suture) for surgically invasive long-term implantation applications. It is used in cardiovascular area.

Rule 8:

“All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended:

- to be placed in the teeth, in which case they are in Class IIa,
- to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III,
- to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III,
- or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.

Clinical Evaluation :

For the clinical evaluation of literature route of MEDDEV 2.7.1Rev.4 has been selected. Clinical Evaluation is given of this technical file.

1.18. Declaration of Conformity

Declaration of Conformity for GMD has been prepared according to EC Directive 93/42/EEC

and approved by General Manager of the company.

The copy of the declaration of Conformity is given on this technical file.

1.20. Notified Body Information

UDEM-TECHNICAL INSPECTION & CERTIFICATION (2292) has been selected as the notified body and certification body.

During CE marking of these products the above declaration of conformity is made on the basis of the Quality Assurance Certificate No. M.2016.106.7035 of UDEM dated 25.10.2016 issued by UDEM TECHNICAL INSPECTION & CERTIFICATION.

1.21. Essential Requirements:

The evidence of the fulfilment of Essential requirements given on Annex I of EC Directive 93/42/EEC, detailed on the Essential Requirements Checklist given on this technical file.

1.22. List of Applicable Standards:

The applicable standards used in compliance with the Essential requirements given on Annex I of EC Directive 93/42/EEC, (detailed on the Essential Requirements Checklist given on TF08 of this technical file) are mainly ISO and EN standards which are harmonised by European Commission for the MDD 93/42/EEC.

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

The list of applicable standards used in design, manufacturing and testing are given of this technical file.

1.23. Risk Analyses

Risk Analyses process of GMD is designed according to EN ISO 14971:2012 and covers all life- cycle process of the product. The Risk Management Activities of GMD are performed according to “Risk Management Instruction”.

1.24.Labels and Instruction for Use

All information required for use of GMD safely is given on the product label and IFU. The device is intended for professional use only and all the applicable information required according to article 13 of Annex I, 93/42/EEC are given on the label and IFU.

The symbols are selected according to EN ISO 15223:2012 The sample layout of IFU and the product label are given on this technical file.

1.25. Conformity Assessment Procedure:

DAMALENE, POLYPROPYLENE manufactured by GMD are CE marked according to Annex II, Article 4 of EC Directive 93/42/EEC. The certification is based on the quality management system of GMD, which is certificated according to ISO 13485:2012.

1.26. Regulatory Requirements for the Product:

EC directive 93/42/EEC is the applicable regulatory requirement for GMD.

1.27. Planned Design Changes

Any design change is not planned. If a change is required, it should be carried out in accordance with GE01021 Değişiklik Yönetimi Prosedürü

1.28. Sale Information

Sale Information for DAMALENE, POLYPROPYLENE

The product has been on the market since 2016. CE marked has been provided from UDEM (2292)

The product has been in the Turkey and European Markets. For 2022 sale informations has been presented below;

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DE-05
			Rev No.	05
	Damalene, POLYPROPYLENE	Polypropylene (Non-Absorbable)	Issue Date	21.07.2023

Labels	Total (Box)
DAMALENE 2-0	(11.455)
DAMALENE 3-0	(10.361)
DAMALENE 5-0	(6.378)
DAMALENE 4-0	(5.691)
DAMALENE 6-0	(3.211)
DAMALENE 1	(3.124)
DAMALENE 0	(3.112)
DAMALENE 2	(1.446)
DAMALENE 7-0	(9,00)

Rev.0 08.07.2016	Initial publish
Rev.1 21.8.2017	Added Product Model Names
Rev.2 24.05.2018	ADDED NEW BRAND “POLYPROPYLENE”
Rev.03 23.10.2018	İtems: Product images, Intended use of the product, Intended user, Patient Population, mechasim of action Design Change, Sale Information have been changed.
Rev 04 20.06.2019	Title Updated
Rev 05 21.07.2023	İtems: Product images, mechanism of action Design Change, Standards, sales Information updated.

Quality Assurance Manager
Aylin KAYA

GMD GROUP
MEDİKAL SAN. VE TİC. A.Ş.
İkitelli O.S.B. Mh. 1533 Sosyal Tesis 2 Sk.
B Blok 1/B 71 Başakşehir / İSTANBUL
İKTİLLİ Y.D. 1484 161 85 79