

	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DK-05
			Rev No.	04
	Damasilk, SILK	Silk (Non-Absorbable)	Issue Date	23.10.2018

1. Product Information

1.1. General Product Name:

Sterile Single Use Non-Absorbable, Synthetic, Multifilament Surgical Suture made of silk

1.2. Product Images



Product codes and Description:

ORIGINAL PRODUCT BARCODE	CODE DESCRIPTION	PRODUCT REFERENCE CODE	BRAND NAME	GMDN CODE	CLASS	SHELF LIFE (MONTHS)
8681665009793	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 0 (BLACK) WITHOUT NEEDLE	DK0-15	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677072211	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLACK) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK02K40	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677074819	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2 (BLACK) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK02K40-90	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677072525	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLACK) 45mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK02K45	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8681665009861	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLACK) 36mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	DK02KDN36	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009878	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DK02M40	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677072723	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DK02M40-90	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677072136	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 17PCS X 45cm USP SIZE 0 (BLACK DYED) WITHOUT NEEDLE	DK0-4X17	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009809	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK0K30	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677072853	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 0 (BLACK) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK0K30-90	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070606	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK0K36	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677072860	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 0 (BLACK) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK0K36-90	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070002	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK0K40	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070040	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DK0M30	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8681677070309	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 36mm 1/2 CIRCLE TAPER POINT NEEDLE	DK0M36	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677072785	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 0 (BLACK) 36mm 1/2 CIRCLE TAPER POINT NEEDLE	DK0M36-90	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009823	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DK0M40	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677071399	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 1 (BLACK) WITHOUT NEEDLE	DK1-15	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677072143	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 17PCS X 45cm USP SIZE 1 (BLACK DYED) WITHOUT NEEDLE	DK1-4X17	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009830	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 6PCS X 75cm USP SIZE 1 (BLACK) WITHOUT NEEDLE	DK1-7X6	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677074048	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (BLACK) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK1K36-90	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070194	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK1K40	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677072730	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (BLACK) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK1K40-90	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009847	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 45mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK1K45	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8681677070057	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 36mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	DK1KDN36	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677074321	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DK1M30	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677074093	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 36mm 1/2 CIRCLE TAPER POINT NEEDLE	DK1M36	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009854	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DK1M40	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677072716	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DK1M40-90	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070972	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 50mm 1/2 CIRCLE TAPER POINT NEEDLE	DK1M50	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009885	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 2-0 (BLACK) WITHOUT NEEDLE	DK2-15	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677072150	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 17PCS X 45cm USP SIZE 2-0 (BLACK) WITHOUT NEEDLE	DK2-4X17	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009991	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK2K26	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070705	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK2K30	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8681677072280	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK2K40	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009892	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DK2M26	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070613	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DK2M30	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009908	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 36mm 1/2 CIRCLE TAPER POINT NEEDLE	DK2M36	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070804	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DK2M40	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009915	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 3-0 (BLACK) WITHOUT NEEDLE	DK3-15	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677071474	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 17PCS X 45cm USP SIZE 3-0 (BLACK) WITHOUT NEEDLE	DK3-4X17	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009922	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 6PCS X 75cm USP SIZE 3-0 (BLACK) WITHOUT NEEDLE	DK3-7X6	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070590	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK3K16	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677072648	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK3K18	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8681677074475	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK3K19	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677074086	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK3K20	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070682	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 22mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK3K22	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009946	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK3K26	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154200015	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 22mm 3/8 CIRCLE NORMAL CUTTING NEEDLE	DK3KD22	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070408	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 16mm 1/2 CIRCLE TAPER POINT NEEDLE	DK3M16	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070293	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DK3M20	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070651	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK DYED) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DK3M22	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070231	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 25mm 1/2 CIRCLE TAPER POINT NEEDLE	DK3M25	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009816	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DK3M26	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8681677072112	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 17PCS X 45cm USP SIZE 4-0 (BLACK) WITHOUT NEEDLE	DK4-4X17	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009960	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK4K16	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677074406	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK4K18	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677075779	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK4K19	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677072754	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK4K20	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070316	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 24mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK4K24	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009953	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 16mm 3/8 CIRCLE NORMAL CUTTING NEEDLE	DK4KD16	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070347	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 16mm 1/2 CIRCLE TAPER POINT NEEDLE	DK4M16	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681665009977	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DK4M20	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070224	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 25mm 1/2 CIRCLE TAPER POINT NEEDLE	DK4M25	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8681665009984	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 13mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK5K13	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070668	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK5K16	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677071450	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 13mm 1/2 CIRCLE TAPER POINT NEEDLE	DK5M13	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677070583	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 16mm 1/2 CIRCLE TAPER POINT NEEDLE	DK5M16	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677071436	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLACK) 13mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK6K13	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677071443	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLACK) 13mm 1/2 CIRCLE TAPER POINT NEEDLE	DK6M13	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677075892	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 35mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK2K35	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677076004	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK1K30	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677076011	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 18mm 1/2 CIRCLE TAPER POINT NEEDLE	DK3M18	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677076295	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 2 (BLACK) 50mm 1/2 CIRCLE TAPER POINT NEEDLE	DK02M50-150	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8681677076301	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 1 (BLACK) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK1K40-100	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677076325	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 35mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK0K35	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677076523	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLACK) WITHOUT NEEDLE	DK02-1X75	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677076592	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 19mm 1/2 CIRCLE TAPER POINT NEEDLE	DK4M19	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677076936	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 35mm 1/2 CIRCLE TAPER POINT NEEDLE	DK2M35	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677077032	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLACK) 48mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK02K48	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677077049	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 48mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK1K48	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677077148	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK4K26	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677077155	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 37mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK2K37	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677077179	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DK4M26	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8681677077216	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 50mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK0K50	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677077360	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 24mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK2K24	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677077377	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK1K36	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677077384	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 17mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK3K17	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677077667	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DK2M20	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677077698	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 22mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK4K22	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677077728	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK5K19	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677077759	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DK3M30	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677077988	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 45mm 1/2 CIRCLE TAPER POINT NEEDLE	DK1M45	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677077995	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 45mm 1/2 CIRCLE TAPER POINT NEEDLE	DK0M45	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8681677078015	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 2-0 (BLACK) 24mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK2K24-45	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677078022	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 3-0 (BLACK) 17mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK3K17-45	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677078039	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 3-0 (BLACK) 22mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK3K22-45	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677078114	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 10PCS X 75cm USP SIZE 4-0 (BLACK) WITHOUT NEEDLE	DK4-10X75	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677078206	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 17PCS X 45cm USP SIZE 0 (BLACK) WITHOUT NEEDLE	DK0-17X45	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677078213	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 17PCS X 45cm USP SIZE 1 (BLACK) WITHOUT NEEDLE	DK1-17X45	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677078220	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK2K36	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677078251	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLACK) 45mm 1/2 CIRCLE TAPER POINT NEEDLE	DK02M45	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677078435	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK3DS30	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677078749	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 60mm STRAIGHT NORMAL CUTTING NEEDLE	DK2GC60	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8681677079166	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 18mm 1/2 CIRCLE TAPER CUT NEEDLE	DK40HRT18	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677079128	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK00DS26	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677079265	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DK20HR22	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677079272	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DK30HR22	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677079340	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 13PCS X 60cm USP SIZE 2-0 (BLACK) WITHOUT NEEDLE	DK20-13X60	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677079357	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 10PCS X 75cm USP SIZE 0 (BLACK) WITHOUT NEEDLE	DK00-10X75	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677079364	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 12mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK50DS12	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677079371	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK30DS36	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677079388	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 2-0 (BLACK) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK20DS26-45	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677079425	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 17mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK40DS17	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8681677079623	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 35mm 1/2 CIRCLE TAPER POINT NEEDLE	DK01HR35	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677079807	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 18mm 1/2 CIRCLE TAPER POINT NEEDLE	DK20HR18	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677079814	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK20DS18	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677079821	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 180cm USP SIZE 0 (BLACK) WITHOUT NEEDLE	DK00-1X180	DAMASILK	13910 – Suture, SILK	Class IIb	60
8681677079838	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 180cm USP SIZE 2-0 (BLACK) WITHOUT NEEDLE	DK20-1X180	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154200121	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 180cm USP SIZE 3-0 (BLACK) WITHOUT NEEDLE	DK30-1X180	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154200220	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 40mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	DK01HC40	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154200435	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK DYED) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK40DS16	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154200442	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK DYED) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK40DS19	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154200459	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 17mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DK40HS17	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8684154200466	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 20mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DK40HS20	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154200473	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DK40HR17	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154200480	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK DYED) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DK40HR20	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154200824	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DK40HR22	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154200831	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 24mm 1/2 CIRCLE TAPER POINT NEEDLE	DK40HR24	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154200954	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 18mm 1/2 CIRCLE TAPER CUT NEEDLE	DK30HRT18	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154200961	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 18mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DK30HS18	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154201081	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK20DS20	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154201098	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 10PCS X 75cm USP SIZE 2-0 (BLACK) WITHOUT NEEDLE	DK20-10X75	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154201104	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 10PCS X 75cm USP SIZE 3-0 (BLACK) WITHOUT NEEDLE	DK30-10X75	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8684154201814	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 35mm 1/2 CIRCLE TAPER POINT NEEDLE	DK00HR35	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202293	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 24mm 1/2 CIRCLE TAPER POINT NEEDLE	DK20HR24	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202309	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 24mm 1/2 CIRCLE TAPER POINT NEEDLE	DK30HR24	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202316	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 35mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK01DS35	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202323	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 24mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK30DS24	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202330	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 5PCS X 45cm USP SIZE 0 (BLACK) WITHOUT NEEDLE	DK00-5X45	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202347	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 5PCS X 45cm USP SIZE 1 (BLACK) WITHOUT NEEDLE	DK01-5X45	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202354	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 5PCS X 45cm USP SIZE 2-0 (BLACK) WITHOUT NEEDLE	DK20-5X45	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202361	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 5PCS X 45cm USP SIZE 3-0 (BLACK) WITHOUT NEEDLE	DK30-5X45	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202552	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 400cm USP SIZE 2 (BLACK) WITHOUT NEEDLE	DK02-400	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8684154202569	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 300cm USP SIZE 1 (BLACK) WITHOUT NEEDLE	DK01-300	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202576	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 300cm USP SIZE 0 (BLACK) WITHOUT NEEDLE	DK00-300	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202583	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 250cm USP SIZE 2-0 (BLACK) WITHOUT NEEDLE	DK20-250	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202590	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLACK) 48mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DK02HS48	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202606	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 40mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	DK00HC40	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202613	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK40DS30	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202620	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 22mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK20DS22	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202798	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK20DS19	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154202804	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLACK) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK60DS19	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154203542	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 30mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DK20HS30	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8684154203559	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 26mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DK20HS26	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154203566	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 30mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DK30HS30	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154203573	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 26mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DK30HS26	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154204211	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 40mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DK00HS40	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154204228	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 40mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DK01HS40	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154204280	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (BLACK) 30mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DK20HS30-90	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154204297	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 400cm USP SIZE 1 (BLACK) WITHOUT NEEDLE	DK01-1X400	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154206048	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 18mm 1/2 CIRCLE TAPER POINT NEEDLE	DK50HR18	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154206376	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 45mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK00DS45	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154207595	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DK00HR22	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8684154207601	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 30mm 3/8 CIRCLE TAPER POINT NEEDLE	DK20DR30	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154207618	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 25mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DK30DS25	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154207625	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 19mm 3/8 CIRCLE TAPER POINT NEEDLE	DK50DR19	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154208318	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DK00HR26	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154208509	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) WITHOUT NEEDLE	DK30-1X75	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154208516	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) WITHOUT NEEDLE	DK00-1X75	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154208523	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 10PCS X 60cm USP SIZE 0 (BLACK) WITHOUT NEEDLE	DK00-10X60	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154208530	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 12PCS X 60cm USP SIZE 3-0 (BLACK) WITHOUT NEEDLE	DK30-12X60	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154208547	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 12PCS X 60cm USP SIZE 0 (BLACK) WITHOUT NEEDLE	DK00-12X60	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154208707	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 50cm USP SIZE 3-0 (BLACK) WITHOUT NEEDLE	DK30-1X50	DAMASILK	13910 – Suture, SILK	Class IIb	60

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8684154208714	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 50cm USP SIZE 2-0 (BLACK) WITHOUT NEEDLE	DK20-1X50	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154208721	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 50cm USP SIZE 0 (BLACK) WITHOUT NEEDLE	DK00-1X50	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154208738	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 50cm USP SIZE 1 (BLACK) WITHOUT NEEDLE	DK01-1X50	DAMASILK	13910 – Suture, SILK	Class IIb	60
8684154214807	DAMASILK: SILK BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 30mm 3/8 CIRCLE NORMAL CUTTING NEEDLE	DK00DC30	DAMASILK	13910 – Suture, SILK	Class IIb	60

1.3. Classification

According to annex IX, rule no. 8 of EC-Directive 93/42/EEC the product category SUTURE 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.

1.4. GMDn Code:

13910 - Silk suture, sterile DESCRIPTION: Fiber made of sterile, single-stranded (monofilament), natural, non-absorbable, raw silk formed by silkworms (typically coated with wax or silicone) used to adjacent (zoom) the wound lips of a soft tissue wound or to suture the wound or ligate soft tissues. It may be accompanied by a needle intended to be discarded after single use. This fiber: provides temporary wound support until the wound has healed enough to withstand normal pressure. Although classified as "non-absorbable" material, it is typically digested by proteolysis after a long period of time. It is a disposable device. CATEGORIES: 03-Dental devices 10-Disposable devices

1.5. Intended use of the product:

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Surgical sutures are sterile threads that are attached to needle and are used for surgical procedures. DAMASILK AND SILK is indicated for general soft tissue approximation and/or ligation, closing and covering suturable wounds under sterile conditions by initially suturing the wound, including use in cardiovascular,

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ophthalmic, microsurgery and neurological surgery microsurgery and neurological surgery.

DAMASILK AND SILK is a sterile, single use, synthetic, multifilament, non absorbable suture made of silk. Silk is a fibrous protein produced by the silkworm Bombyx mori. The protein is crystalline and oriented in axial direction.

Silk suture material is a high molecular weight linear polymer, which is extruded in to thin filaments and braided in to sutures of various diameters.

DAMASILK AND SILK is available in a range of gauge sizes and lengths, non-needle or attached to stainless steel needles of varing types and sizes.

The product range of DAMASILK AND SILK varies as the diameter of sterile non absorbable surgical suture strands from 0,070 mm to 0,600 mm. The length of sterile non absorbable surgical suture strands varies from 45 cm to 180 cm. The length of needles varies from 10 mm to 60 mm. The shape of needles varies from 3/8 1/2 circle or straight. The different variants are listed in the PRODUCT LIST of NONABSORBABLE SUTURE.

sutures elicits minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrious connective tissue. While DAMASILK AND SILK sutures is non absorbed progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of the sutures tensile strength over time.

Sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Phramacoppeia (EP) for non-absorbable surgical sutures.

DAMASILK AND SILK sutures are available colored black with Logwood extract.

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- A b s o r b a b l e Sutures except for a slight oversize in diameter

1.6. Intended User

The device should used by physician and/or surgeons.

1.7. Patient population

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, ophthalmic, microsurgery and neurological surgery microsurgery and neurological surgery.

The target group of this device is patients who are need to ligate/close/cover the wounds due to cardiovascular, ophthalmic, microsurgery and neurological surgery microsurgery and neurological surgery.

1.8. The Contents of the Product

The device does not include chemicals, medicinal substance and blood components. The

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declaration about contents is given in Declarations.

1.9. 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.

1.10. Mechanism of Action

Suture elicits minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While suture is not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of the sutures tensile strength over time.

1.11. Components and Raw Materials of product:

Surgical Suture

Surgical Needle

Manufacturer/Supplier	Material
Mazeferro	Siliconized silk Uncoated Black (Logwood extract)
Quality Needles Pvt	Stainless Steel 302
Anging Kangmingna	Big Over Wrap and Small Over Wrap
Endustri Maatbacılık	Boxes

1.2. Accessories Information

There is no accessories.

1.3.Suitability of Raw Material

Raw materials are supplied from the suppliers given in 1.4. Components of product. Raw materials analysis reports are given in Test Reports

1.4.Indication, Contraindication and Adverse Reactions

• Indications:

DAMASILK AND SILK sutures are indicated for use in general soft tissue approximation and/or ligation.

• Contraindications:

The use of DAMASILK AND SILK is contraindicated in patients with known sensitivities or allergies to silk. Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, sutures should not be used where permanent retention of tensile strength is required

• Adverse Reactions

Adverse effects associated with the use of this device include: wound dehiscence, gradual Loss of tensile strength over time, allergic response in patients with known sensitivities to silk, calculi formation when prolonged contact with salt solutions occurs, enhanced bacterial

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infectivity, minimal acute inflammatory reaction, and transitory local irritation.

* One package unit of DAMASILK AND SILK contains 12 single pouches.

1.5. Material Specifications:

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

- **Thread**

(Siliconized silk, multifilament)

1.6. The following specifications are met:

Appearance:

The non-absorbable suture is composed of silk filaments that are braided or twisted in a suitable construction for the intended size to meet current USP specifications. The silk sutures have been dyed black with Haematoxylin (Logwood extract).

Name:

Siliconized silk

Additives:

The quantity of colour additive is not to exceed 1.00 % by weight of the suture.

The Logwood extract conforms to 21 CFR 73.1410 and does not exceed 1.0 % (w/w) of suture.

Dyestuffs

Black coloured threads

Silk sutures dyed with Haematoxylin(Logwood extract). The diestuff meets all FDA requirements: reference Federal Register, title 21,73.1410.

Formula of Haematoxylin: C₁₆ H₁₄ O₆ + H₂O

Coating

Uncoated

Physical Specification

SUTURE 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.

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Suture Biological Physical Properties: SILK

EP SIZE	USP SIZE	DIA METER			Knot pull tensile strength		Suture-Needle tensile strength	
		A Dia meter average (mm)	B		C Average values kgf (N)	D Min values kgf (N)	A Average (kgf) (N)	B Min values (kgf) (N)
			Min values (mm)	Max values (mm)				
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.

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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.)	Individual (in N) (Min.)
	0.1	11-0	0.007	0.005	0.049
	0.2	10-0	0.014	0.010	0.098
0.4	0.3	9-0	0.021	0.015	0.147
0.5	0.4	8-0	0.050	0.025	0.245
0.7	0.5	7-0	0.080	0.040	0.392
1	0.7	6-0	0.17	0.08	0.784
1.5	1	5-0	0.23	0.11	1.08
2	1.5	4-0	0.45	0.23	2.25
3	2	3-0	0.68	0.34	3.33
3.5	3	2-0	1.10	0.45	4.41
4	3.5	0	1.50	0.45	4.41
5	4	1	1.80	0.60	5.88
6 and larger	5 and larger	2 and larger	1.80	0.70	6.86

Retention ratio of tensile strength

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

NEEDLE:

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

For Analysis Certificates

Tipping solution Araldite

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

Araldite 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.

Specification of primary and secondary packaging material

packaging material is made from a pouch made of medical paper For Analysis Certificates see Test Reports

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. (Clinical and Biological Evaluation)

Biocompatibility Tests of the Raw Materials for Medical Device (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 ISO10993-1, based on a risk analysis. Where existing data are adequate, additional testing is not

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required. Clinical and Biological Evaluation)

Biocompatibility Test Matrix

DEVICE CATEGORIES			BIOLOGICAL EFFECT									
				Cytotoxicity	Sensitization	Irritation/Intracutaneous	Acute Systemic Toxicity	Subchronic Toxicity	Genotoxicity	Implantation		
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				
		C	x	x	x	x	x	x				
	Circulating Blood	A	x	x	x	x		x				
		B	x	x	x	x	x	x	x			
		C	x	x	x	x	x	x	x			
IMPLANT DEVICES	Tissue/Bone	A	x	x	x							
		B	x	x	x	x	x	x				
		C	x	x	x	x	x	x				
	Blood	A	x	x	x	x	x	x				
		B	x	x	x	x	x	x				
		C	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:

Product	Classification	Required Tests
DAMASILK and SILK	Implant Devices Tissue/Bone	Cytotoxicity

The results of the biocompatibility tests on non-absorbable, silk suture demonstrate the excellent biocompatibility of the material and also demonstrate that the ETO sterilization does not have any negative effects on the material.

Based on the clinical experiences with the product 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 NONABSORBABLE SUTURE can be regarded as biocompatible and suitable for a clinical application.

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1.11. Biodegradation for Medical Device NONABSORBABLE SUTURE.

multifilament surgical suture is not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of the sutures tensile strength over time.

1.12. Manufacturing Process:

Manufacturing is performed at the İkitelli OSB, İsdök Sosyal Tesis 2 sk. B Blok 1 B 7 Başakşehir/İstanbul, Turkey. The production consists 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

DAMASILK, SILK 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 11135-1:2007. Main routine sterilization parameters are 55 °C %30 Humidity with a gas injection period of 6 hours.

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

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Packaging into cartons

Twelve sutures pouches are packed into a carton and labelled. Each carton is cellophane wrapped. Sixty 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 routine 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:

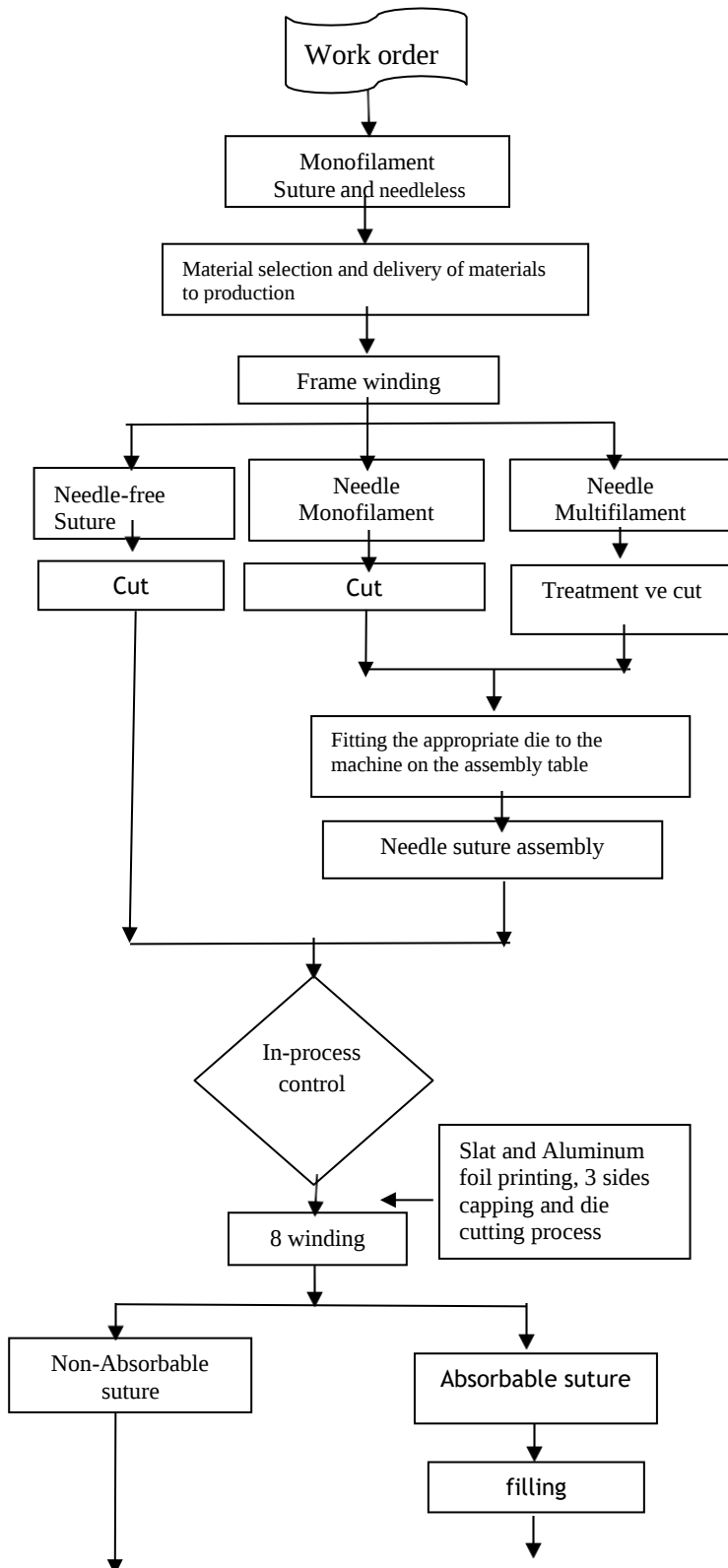
- 4 mg in the first 24 h;
- 60 mg in the first 30 d.

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

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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-Frame 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

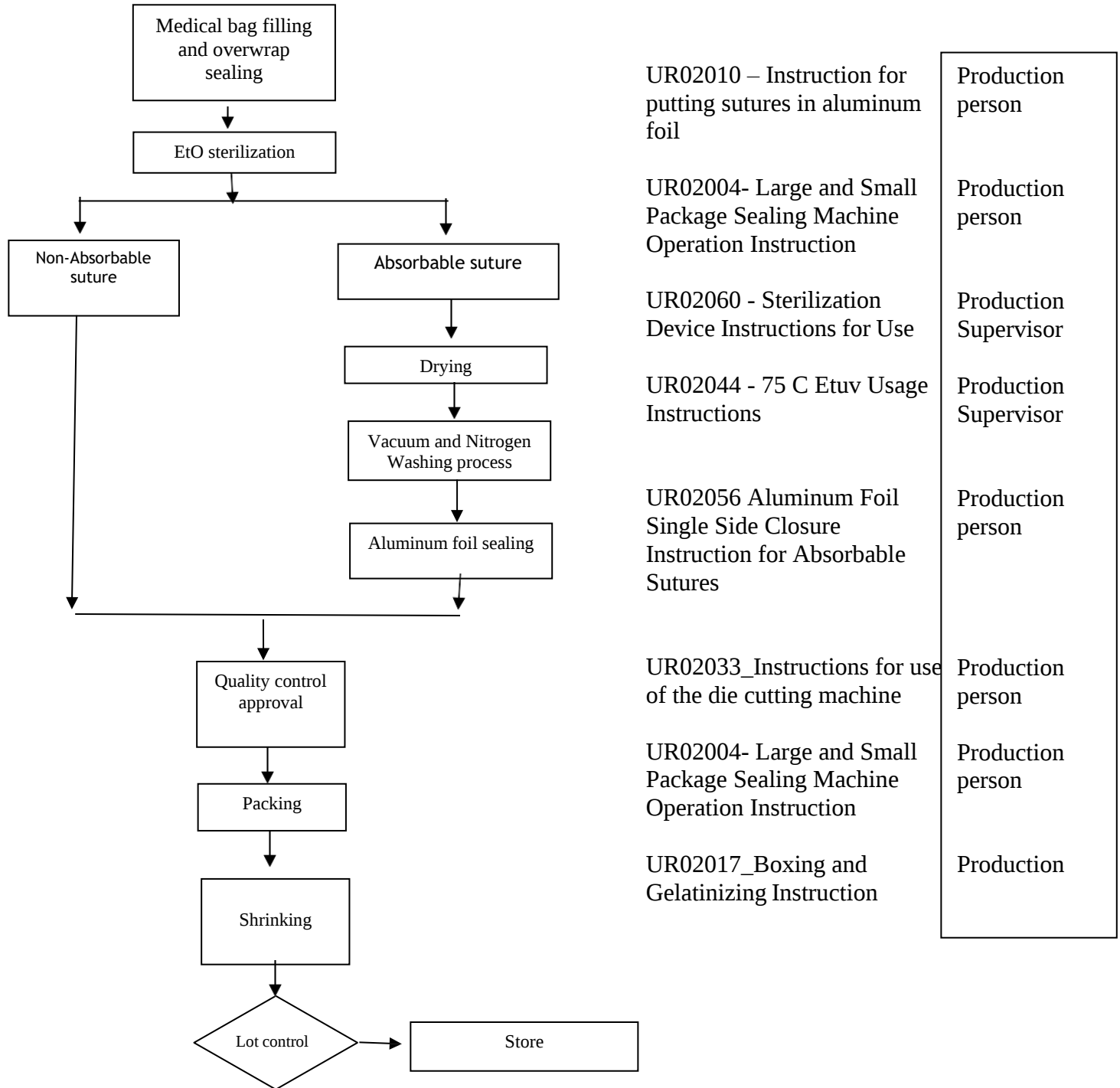
QA Manager

QA Manager

Production
personnel

Production
personnel

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

1.7. Product and Test Specifications:

The silk range of sutures started to successfully produced and extensively used in 2016.

The following tests are specified as final batch release controls according to USP

29: Table: Test specifications and Lot results.

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Test Parameter	Method	Lot: 23E01K067		Lot: 23D02K006	
		Code: DK5M13		Code: DK02M40	
		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 DAMASILK and SILK lots given on the above table are given on Test reports.

1.8. Stability/Aging Test and Product Lifetime:

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.

1.9. Product Tests (Performance) :

The relevant tests and reports are given on Test Reports

1.10. Clinical Evaluation :

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

1.11. 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 of

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this technical file) are mainly ISO and EN standards which are harmonised by European Commission for the MDD 93/42/EEC.

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

1.23. Risk Analysis

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 this technical file.

1.25. Conformity Assessment Procedure:

SUTURE manufactured by GMD are CE marked according to Annex II, excluding Article 4 of EC Directive 93/42/EEC. The certification is based on 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 İnförmatıon for DAMASILK& SILK

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 2018 sale informations has been presented below;

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Product Name	Package	Quantity
DAMASILK : 1 90CM NEEDLE 40MM ROUND	BOX	89
DAMASILK : 2 90CM NEEDLE 40MM ROUND	BOX	87
DAMASILK : 4-0 45CM X 17	BOX	4
DAMASILK : SILK 0 90CM NEEDLE 30MM CUTTING	PCS	86
DAMASILK : SILK 0 90CM NEEDLE 36MM ROUND	PCS	85
DAMASILK : SILK 0 Black 150cm without Needle	BOX	1
DAMASILK : SILK 0 Black 75cm Needle Rev.C 3/8 40mm	BOX	613
DAMASILK : SILK 0 Black 75cm Needle T.P. 1/2 40mm	BOX	273
DAMASILK : SILK 1 Black 17x45cm without Needle	BOX	2
DAMASILK : SILK 1 Black 75cm Needle Rev.C 3/8 40mm	BOX	611
DAMASILK : SILK 1 Black 75cm Needle T.P. 1/2 40mm	BOX	242
DAMASILK : SILK 2 Black 75cm Needle Rev.C 3/8 40mm	BOX	390
DAMASILK : SILK 2 Black 75cm Needle T.P. 1/2 40mm	BOX	651
DAMASILK : SILK 2-0 Black 17x45cm without Needle.	BOX	45
DAMASILK : SILK 2-0 Black 75cm Needle T.P. 1/2 26mm	BOX	193
DAMASILK : SILK 2-0 Black 75cm Needle T.P. 1/2 30mm	BOX	141
DAMASILK : SILK 3-0 75CM NEEDLE 18MM CUTTING	BOX	331
DAMASILK : SILK 3-0 Black 150cm without Needle	BOX	5
DAMASILK : SILK 3-0 Black 17x45cm without Needle	BOX	32
DAMASILK : SILK 3-0 Black 75cm Needle Rev.C 3/8 16mm	BOX	15
DAMASILK : SILK 3-0 Black 75cm Needle Rev.C 3/8 26mm	BOX	1183
DAMASILK : SILK 3-0 Black 75cm Needle T.P. 1/2 26mm	BOX	770
DAMASILK : SILK 4-0 Black 75cm Needle Rev.C 3/8 16mm	BOX	286
DAMASILK : SILK 5-0 Black 75cm Needle Rev.C 3/8 13mm	BOX	100
DAMASILK : SILK 5-0 Black 75cm Needle Rev.C 3/8 16mm	BOX	85
DAMASILK : SILK 6-0 Black 75cm Needle Rev.C 3/8 13mm	BOX	135
DAMASILK : SILK 6-0 Black 75cm Needle T.P. 1/2 13mm	BOX	2
DAMASILK : SLIK 2-0 Black 75cm Needle Rev.C 3/8 26mm	BOX	1681
DAMASILK: SILK 0 90CM NEEDLE 36MM CUTTING	BOX	88
DAMASILK: SILK 1 90CM NEEDLE 40MM CUTTING	BOX	80
DAMASILK: SILK 4-0 75CM NEEDLE 20MM CUTTING	BOX	430
DAMASILK: silk 2 45mm 75cm cutting	BOX	100
SJ SILK : SILK 2-0 75CM NEEDLE 20MM CUTTING	BOX	150
SJ SILK : SILK 3-0 75CM NEEDLE 18MM CUTTING	BOX	160
SJ.PGA : PGA 2 75CM NEEDLE 50MM ROUND	BOX	212
THREAD SILK SIZE 5-0 NEEDLE Reverse cutting 3/8 CIRCLE 13MMM	BOX	100

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Rev. History

Rev.0 08.07.2016	Initial publish
Rev.1 21.8.2017	Added Product Model Names
Rev.2 22.05.2018	ADDED NEW BRAND "SILK"
Rev.3 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

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