

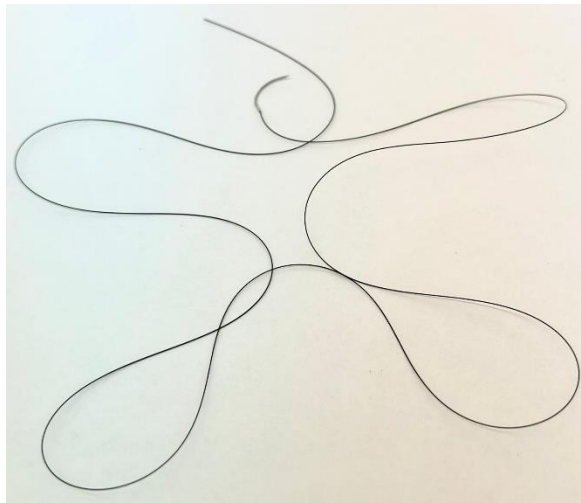
	Gmd Group Medikal San. Ve Tic. A.Ş		Ref No.	DN-05
	Department	Device master file	Rev No.	05
	DAMALON	Polyamide 6-6.6 (Non-Absorbable)	Issue Date	21.07.2023

1.Product Information

1.1. General Product Name:

Sterile Single Use Non-Absorbable, Synthetic, Monofilament Surgical Suture made of Polyamide.

1.2.Product images



Product codes and Description:

ORIGINAL PRODUCT BARCODE	CODE DESCRIPTION	PRODUCT REFERENCE CODE	BRAND NAME	GMDN CODE	CLASS	SHELF LIFE (MONTHES)
8681677073218	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLACK) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN02K40	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677072532	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLACK) 45mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN02K45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681665009045	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DN02M40	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8681677072747	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DN02M40-90	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677074727	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 2 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE (LOOPED ON)	DN02ML40-150	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681665009007	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN0K30	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070361	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN0K36	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677072839	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 0 (BLACK) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN0K36-90	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070996	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN0K40	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070125	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 25mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	DN0KDN25	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681665009014	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DN0M30	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677073287	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 0 (BLACK) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DN0M30-90	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070941	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 36mm 1/2 CIRCLE TAPER POINT NEEDLE	DN0M36	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8681677070354	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DN0M40	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677071481	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 0 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE (LOOPED ON)	DN0ML40-150	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677072822	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (BLACK) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN1K30-90	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677074116	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN1K36	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677072846	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (BLACK) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN1K36-90	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681665009021	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN1K40	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070965	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DN1M30	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677074826	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (BLACK) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DN1M30-90	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681665009038	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DN1M40	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677072174	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 1 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DN1M40-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8681677072761	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DN1M40-90	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677071498	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 1 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE (LOOPED ON)	DN1ML40-150	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677074703	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN2K20	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681665009052	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN2K26	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070378	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN2K30	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677071429	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 26mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	DN2KDN26	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070217	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DN2M26	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070729	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DN2M30	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677071504	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 2-0 (BLACK) 26mm 1/2 CIRCLE TAPER POINT NEEDLE (LOOPED ON)	DN2ML26-150	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070491	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 60mm STRAIGHT REVERSE CUTTING NEEDLE	DN2SK60	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8681677074710	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN3K20	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070620	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 24mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN3K24	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070576	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 25mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN3K25	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681665009069	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN3K26	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681665009076	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 25mm 1/2 CIRCLE TAPER POINT NEEDLE	DN3M25	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677071160	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DN3M26	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070149	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN4K16	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677074352	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 17mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN4K17	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070675	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN4K20	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681665009083	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 16mm 3/8 CIRCLE NORMAL CUTTING NEEDLE	DN4KD16	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8681665009090	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 16mm 1/2 CIRCLE TAPER POINT NEEDLE	DN4M16	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677071177	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DN4M20	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677072587	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DN4M20B	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070927	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DN4M22	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677071191	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 13mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN5K13	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070156	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK DYED) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN5K16	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681665009106	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 16mm 3/8 CIRCLE NORMAL CUTTING NEEDLE	DN5KD16	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070033	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 13mm 1/2 CIRCLE TAPER POINT NEEDLE	DN5M13	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070637	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 16mm 1/2 CIRCLE TAPER POINT NEEDLE	DN5M16	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681665009113	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DN5M17	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8681677070699	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLACK) 13mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN6K13	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677070071	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLACK) 13mm 1/2 CIRCLE TAPER POINT NEEDLE	DN6M13	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677076332	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DN3M20	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677076882	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 35mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN0K35	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677076899	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN1K30	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677076905	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 3-0 (BLACK) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN3K18-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677077438	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN5K19	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677077650	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 0 (BLACK) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN0K30-90	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677077704	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 35mm 1/2 CIRCLE TAPER POINT NEEDLE	DN0M35	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677077711	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN4K19	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8681677077803	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN3K19	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677077810	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 4-0 (BLACK) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN4K19-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677077865	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 3-0 (BLACK) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN3K19-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677077872	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 35mm 1/2 CIRCLE TAPER POINT NEEDLE	DN1M35	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677078152	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 15mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN5K15	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677078169	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 2-0 (BLACK) 25mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN2K25-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677078268	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN5K20	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677079074	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 17mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN5K17	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677079197	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK DYED) 18mm 1/2 CIRCLE TAPER CUT NEEDLE	DN40HRT18	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677079135	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DN3M17	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8681677079142	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DN4M17	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677079289	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN50DS16	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677079296	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 18mm 1/2 CIRCLE TAPER CUT NEEDLE	DN50HRT18	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677079449	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 18mm 1/2 CIRCLE TAPER CUT NEEDLE	DN40HSY18	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677079548	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 3-0 (BLACK) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN30DS26-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677079555	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 3-0 (BLACK) 25mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN30DS25-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677079562	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN30DS30	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677079593	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 5-0 (BLACK) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN50DS16-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677079609	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 25mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN20DS25	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8681677079616	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN40DS18	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8681677079913	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 3-0 (BLACK) 26mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DN30HS26-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154200275	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLACK) 17mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN60DS17	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154200374	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN20DS18	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154200534	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK DYED) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DN40HR20	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154200541	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK DYED) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DN40HR17	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154200558	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK DYED) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN40DS16	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154200565	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK DYED) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN40DS19	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154200572	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 17mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DN40HS17	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154200589	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 20mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DN40HS20	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154200787	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 6-0 (BLACK) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN60DS16-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8684154200879	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 19mm 1/2 CIRCLE TAPER POINT NEEDLE	DN40HR19	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154200886	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 20mm 1/2 CIRCLE TAPER CUT NEEDLE	DN40HRT20	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154200893	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 20mm 3/8 CIRCLE NORMAL CUTTING NEEDLE	DN40DC20	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154200909	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 22mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN30DS22	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154201531	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 24mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN40DS24	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154201548	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 4-0 (BLACK) 24mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN40DS24-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154201739	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLACK) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN60DS19	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154201838	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN30DS18	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154201845	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 2-0 (BLACK) WITHOUT NEEDLE	DN20-150	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154202392	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 25mm 1/2 CIRCLE TAPER POINT NEEDLE	DN20HR25	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8684154202408	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 35mm 1/2 CIRCLE TAPER POINT NEEDLE	DN20HR35	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154202415	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DN20HR40	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154202422	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DN30HR22	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154202439	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DN30HR30	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154202446	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 35mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN01DS35	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154202453	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 35mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN20DS35	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154202538	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 300cm USP SIZE 2-0 (BLACK) WITHOUT NEEDLE	DN20-300	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154202545	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 300cm USP SIZE 0 (BLACK) WITHOUT NEEDLE	DN00-300	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154202668	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 30mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DN00HS30	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154202675	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 30mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DN01HS30	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8684154202774	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN30DS16	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154202781	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN20DS19	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154203245	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 1 (BLACK) WITHOUT NEEDLE	DN01-1X150	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154203320	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 60mm STRAIGHT REVERSE CUTTING NEEDLE	DN30GS60	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154203498	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (BLACK) 40mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DN01HS40	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154203504	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 40mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DN00HS40	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154203726	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (UNDYED) 40mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DN00HS40U	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154203733	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (UNDYED) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DN00HR40U	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154203740	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (UNDYED) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN00DS40U	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154203757	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (UNDYED) 25mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN20DS25U	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8684154203764	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (UNDYED) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DN20HR26U	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154203771	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (UNDYED) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN30DS20U	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154203788	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (UNDYED) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DN30HR22U	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154203795	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (UNDYED) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN40DS20U	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154203801	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (UNDYED) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DN40HR20U	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154204419	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 24mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN20DS24	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154204426	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN20DS40	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154204433	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLACK) 34mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN20DS34	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154204440	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN30DS36	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154204457	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 16mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DN40HS16	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8684154204587	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (BLACK) 30mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DN20HS30-90	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154205973	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (BLUE) 25mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN20DS25B	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154205980	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLUE) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN30DS20B	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154205997	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLUE) 13mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN50DS13B	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154206000	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 4-0 (BLUE) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN40DS19B-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154206147	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 10-0 (BLACK) 7mm 3/8 CIRCLE SPATULA MICRO POINT DOUBLE NEEDLE	DN10DSPM7-D-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154206154	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 10-0 (BLACK) 6mm 3/8 CIRCLE SPATULA MICRO POINT DOUBLE NEEDLE	DN10DSPM6-D-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154206420	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 0 (BLUE) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN00DS30B-90	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154207090	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 27mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN00DS27	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154207236	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLUE) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN40DS20B	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8684154207502	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLACK) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DN02HR20	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154207519	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 18mm 1/2 CIRCLE TAPER POINT NEEDLE	DN00HR18	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154207526	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (BLACK) 26mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DN00HS26	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154207533	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 37mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN30DS37	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154207540	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLACK) 17mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DN60HS17	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154207557	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLACK) 13mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DN60HR13-D	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154207632	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 3-0 (BLACK) WITHOUT NEEDLE	DN30-1X150	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154207649	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 2 (BLACK) WITHOUT NEEDLE	DN02-1X150	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154208325	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 2-0 (BLACK) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN20DS26-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154208332	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (BLACK) 16mm 1/2 CIRCLE TAPER POINT NEEDLE	DN30HR16	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8684154208745	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 12mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN50DS12	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154208752	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (BLACK) 12mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN60DS12	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154208769	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (BLACK) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN01DS40-90	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154208776	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (BLACK) 40mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DN02HS40	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154208820	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 6-0 (BLACK) 13mm 3/8 CIRCLE REVERSE CUTTING (PRIME POINT) NEEDLE	DN60DSR13-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154208837	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 6-0 (BLACK) 11mm 3/8 CIRCLE REVERSE CUTTING (PRIME POINT) NEEDLE	DN60DSR11-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154208844	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (BLACK) 19mm 3/8 CIRCLE REVERSE CUTTING (PRIME POINT) NEEDLE	DN50DSR19	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154208851	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (BLACK) 19mm 3/8 CIRCLE REVERSE CUTTING (PRIME POINT) NEEDLE	DN40DSR19	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154208905	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 6-0 (BLACK) 12mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN60DS12-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
8684154208912	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 7-0 (BLACK) 12mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN70DS12	DAMALON	38000 – Nylon suture, single filament	Class IIb	60

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8684154214814	DAMALON: PA MONOFILAMENT NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 5-0 (BLACK) 15mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DN50DS15-45	DAMALON	38000 – Nylon suture, single filament	Class IIb	60
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1.3.Gmdn Code:

38847; Nylon suture, single filament DESCRIPTION: A sterile, single-stranded (monofilament), synthetic, absorbable, nylon (a polymer of polyamide) fiber 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 heals enough to withstand normal pressure and is eventually absorbed by hydrolysis. It is a disposable device. After wound healing is completed, it can be removed from the tissue or left in the tissue, covering it with fibrous connective tissue over time.

CATEGORIES: 03-Dental devices 10-Disposable devices

1.4.Intended use of the product:

DAMALON AND POLYAMIDE sutures are sterile threads that are attached to needle and are used for surgical procedures. DAMALON AND POLYAMIDE sutures are indicated for use in general soft tissue approximation and /or ligation, including use in, ophthalmic, microsurgery.

DAMALON AND POLYAMIDE 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 0,070 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 6 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 DAMALON AND POLYAMIDE.

DAMALON AND POLYAMIDE sutures elicit minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While DAMALON AND POLYAMIDE sutures is non absorbed progressive degradation in vivo may result in gradual loss of the sutures tensile strength over time.

DAMALON AND POLYAMIDE sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopia (EP) for non-absorbable surgical sutures.

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

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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.

1.5. 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 use 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.

1.8.Mechanism of Action

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

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

Manufacturer/Supplier	Material
G.Krahmer Gmbh	Polyamide 6-6.6
Quality Needles Pvt Co	Stainless Steel 300 (Serialnumber)
FTM Ambalaj	packing (medical paper)
Panograf Ltd	Paper (card)

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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 product. Raw materials analysis reports are given in Test Reports

1.12.. Indication, Contraindication and Adverse Reactions

1.12.1. Indications:

DAMALON AND POLYAMIDE sutures are indicated for use in general soft tissue approximation and ligation. Finer sizes used in ophthalmic and microsurgery procedures.

1.12.2.Contraindications:

The use of DAMALON AND POLYAMIDE : 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.

1.12.3.Adverse Reactions

Adverse effects associated with the use of this device include: wound dehiscence, gradual Loss of tensile strength over time, calculi formation when prolonged contact with salt solutions occurs, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation.

* One package unit of DAMALON AND POLYAMIDE 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 (Monofilament, Polyamide) The following specifications are met: Appearance:

The non-absorbable suture is composed of polyamide that are monofilament in a suitable construction for the intended size to meet current USP specifications. The polyamide sutures has been dyed black with Haematoxylin.

Name:

Polyamide 6-6.6

Additives:

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

Dyestuffs

Black coloured threads

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Polyamide 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

DAMALON AND POLYAMIDE 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.

Suture Biological Physical Properties : Polyamide

Anm a No	USP No	ÇAP LİMİTLERİ			DÜĞÜM KOPMA MUKAVEMETİ		İĞNENİN SÜTÜRDEN AYRILMA KUVVETİ	
		A Ortalama Çap (mm)	B		C Ortalama kgf (N)	D Herbir Değer kgf (N)	A Ortalama (kgf) (N)	B Herbir Değer (kgf) (N)
			En Az Değer (mm)	En Çok Değer (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

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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.

Table 1. Standard Needle Attachment for Absorbable and Nonabsorbable Sutures

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

Retention ratio of tensile strength

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

1.13.2 NEEDLE:

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

1.13.3 Specification of packaging material

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

Certificates see Test Reports

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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. (Clinical and Biological Evaluation)

1.15. 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 ISO 10993-1, based on a risk analysis. Where existing data are adequate, additional testing is not required. (TF13 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					
		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					

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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
DAMALON AND POLYAMIDE	Implant Devices Tissue/Bone C-Permanent	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 DAMALON AND POLYAMIDE can be regarded as biocompatible and suitable for a clinical application.

1.16. Biodegradation for Medical Device DAMALON AND POLYAMIDE.

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.

1.17. 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 manually 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

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Clean Room.

One package unit of DAMALON AND POLYAMIDE contains 12 single pouches.

Sterilization

DAMALON AND POLYAMIDE 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.

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 Test Reports.

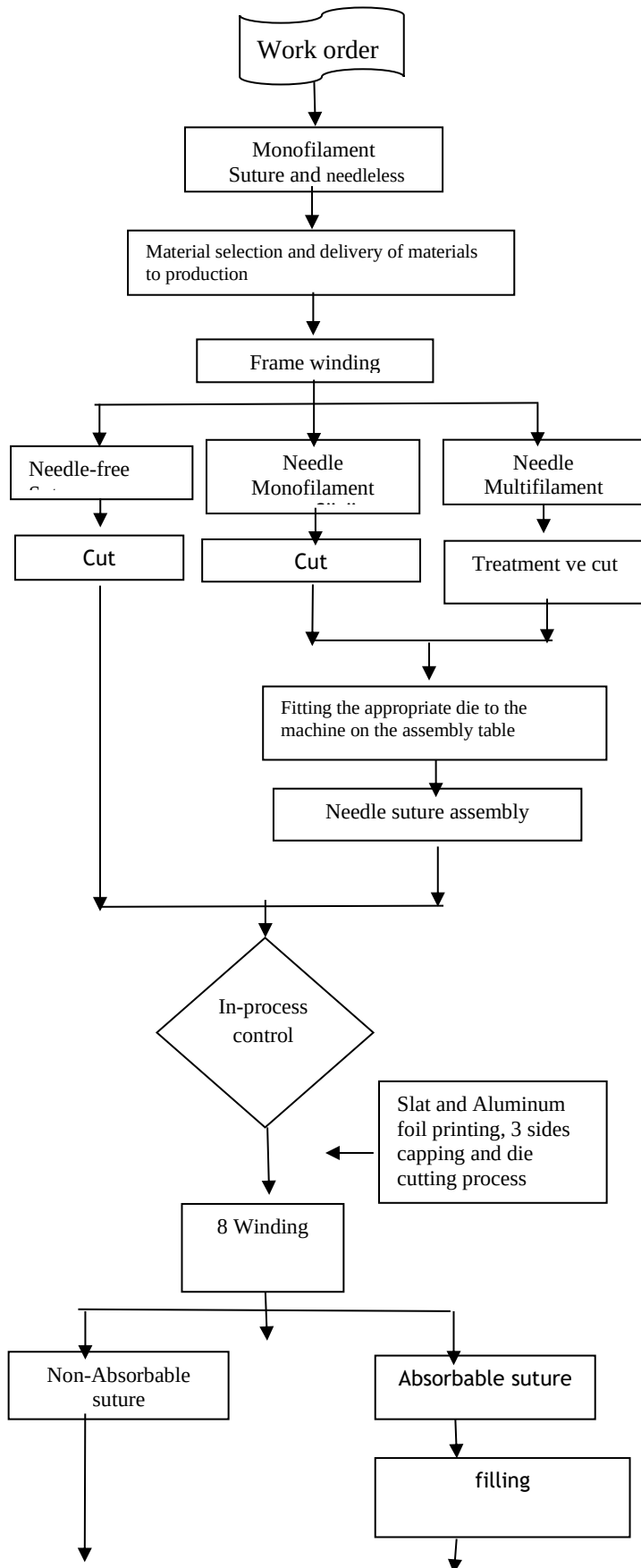
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Manufacturing Flow Chart

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-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

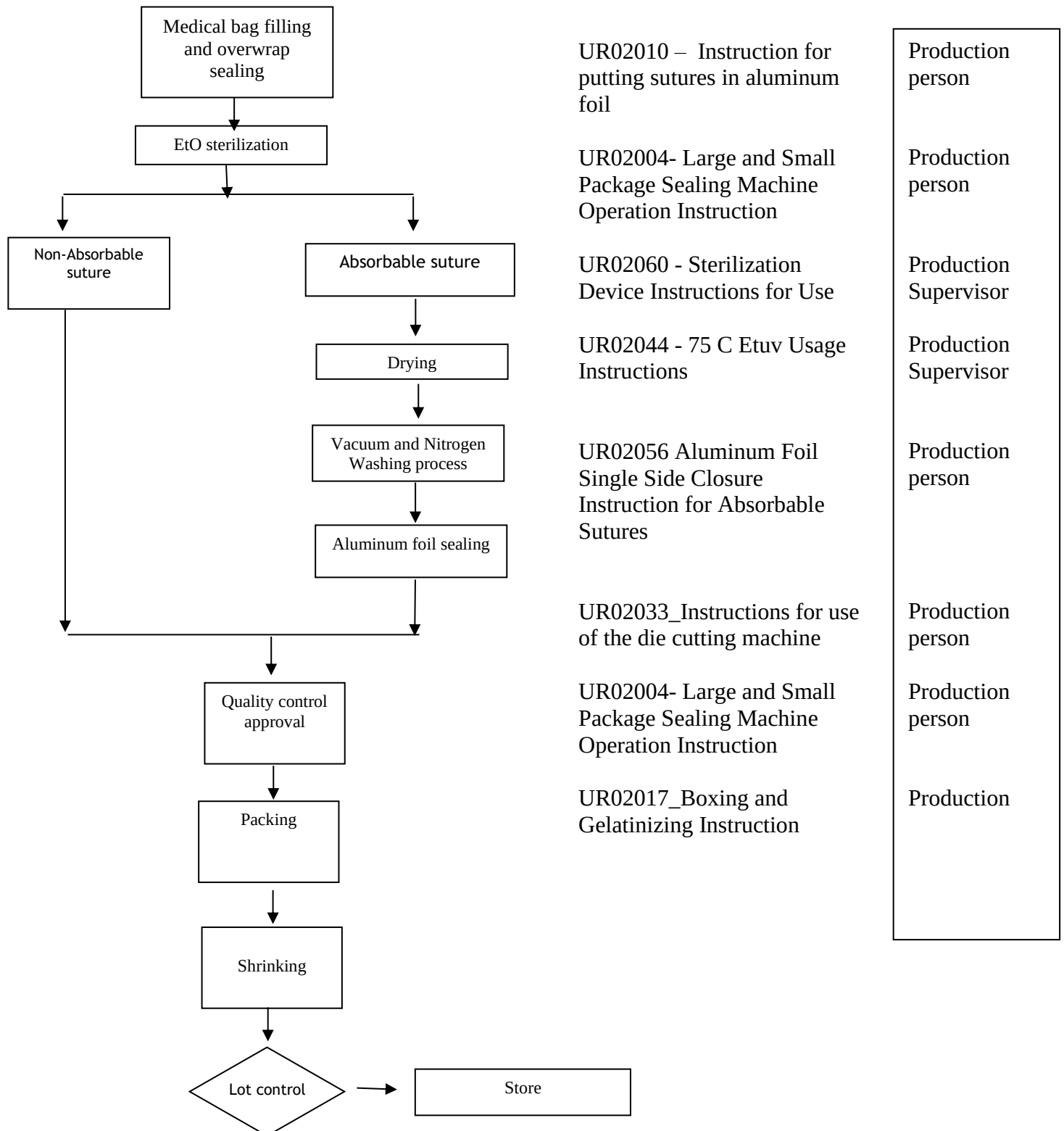
QA Manager

QA Manager

Production
personnel

Production
personnel

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

1.18.Product and Test Specifications:

The DAMALON AND POLYAMIDE range of sutures started to successfully produced and extensively used in 2016.

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

29: Table: Test specifications and Lot results.

Test Parameter	Method	Lot: 23E01N129		Lot: 23E02N090	
		Code: DN20DS24		Code: DN40DS19	
		Limit	result	limit	result
Needle Attachment	USP 25	11,0	23,8	4,5	11.3
Sterility Test	USP 25	sterile	sterile	sterile	sterile

1.19.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.

1.20.Product Tests(Performance) :

The relevant tests and reports are given on Test Reports

1.21.The Product 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.

1.22.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.

1.23.Declaration of Conformity

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

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and approved by General Manager of the company.

The copy of the declaration of Conformity is given on t echnical file.

1.24. 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. MD.2016.106.7035 of UDEM dated 25.10.2016 issued by UDEM TECHNICAL INSPECTION & CERTIFICATION .

1.25. 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.

1.26. 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.

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

1.27. 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”.

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1.28.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.

1.29.Conformity Assessment Procedure:

SUTURE manufactured by GMD are CE marked according to Annex II, 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.

1.30.Regulatory Requirements for the Product:

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

1.31.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

1.32.Sale Information

Sale Information for DAMALON

The product has been in 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;

Product Name	Package	Quantity
DAMALON : PA 0 Black 75cm Needle Rev.C 3/8 40mm	BOX	732
DAMALON : PA 0 loop Black 150cm Needle T.P. 1/2 40mm	BOX	170
DAMALON : PA 1 Black 75cm Needle Rev.C 3/8 40mm	BOX	150
DAMALON : PA 1 Black 75cm Needle T.P. 1/2 40mm	BOX	505
DAMALON : PA 1 loop Black 150cm Needle T.P. 1/2 40mm	BOX	1399
DAMALON : PA 2 Black 75cm Needle T.P. 1/2 40mm	BOX	150
DAMALON : PA 2-0 Black 75cm Needle Rev.C 3/8 26mm	BOX	1187
DAMALON : PA 2-0 Black 75cm Needle T.P. 1/2 26mm	BOX	651
DAMALON : PA 2-0 Black 75cm Needle T.P. 1/2 30mm	BOX	7
DAMALON : PA 3-0 Black 75cm Needle Rev.C 3/8 25mm	BOX	2
DAMALON : PA 3-0 Black 75cm Needle Rev.C 3/8 26mm	BOX	833
DAMALON : PA 3-0 Black 75cm Needle T.P. 1/2 25mm	BOX	61
DAMALON : PA 3-0 Black 75cm Needle T.P. 1/2 26mm	BOX	410
DAMALON : PA 4-0 Black 75cm Needle Rev.C 16mm	BOX	67
DAMALON : PA 4-0 Black 75cm Needle Rev.C 3/8 20mm	BOX	405

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DAMALON : PA 4-0 Black 75cm Needle T.P. 1/2 20mm	BOX	100
DAMALON : PA 5-0 Black 75cm Needle Rev.C 3/8 16mm	BOX	150
DAMALON : PA 6-0 Black 75cm Needle Rev.C 3/8 13mm	BOX	250
DAMALON: P.A 0 75CM NEEDLE 30MM ROUND	BOX	80
DAMALON: P.A 1 90CM NEEDLE 30MM CUTTING	BOX	50
DAMALON: P.A 1 90CM NEEDLE 40MM ROUND	BOX	90
DAMALON: P.A 2 75CM NEEDLE 40MM CUTTING	BOX	100
DAMALON: p.a 2 45mm 75cm cutting	BOX	102

Rev. History

Rev.0 25.04.2016	Initial publish
Rev.1 15.8.2017	General changes
Rev.2 21.8.2017	Added Product Model Names
Rev.3 22.05.2018	ADDED new brand name "POLYAMIDE "
Rev.04 23.10.2018	Items: Product images, Intended use of the product, Intended user, Patient Population, mechanism of action Design Change, Sale Information have been changed.
Rev05 20.06.2019	Title Updated

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