



GMD Group Medikal San. Ve Tic. A.Ş

Revision
Date

15.03.2024

Ref No.

DC-06

Damacryl
and PGA

PGA (Absorbable)

Rev No.

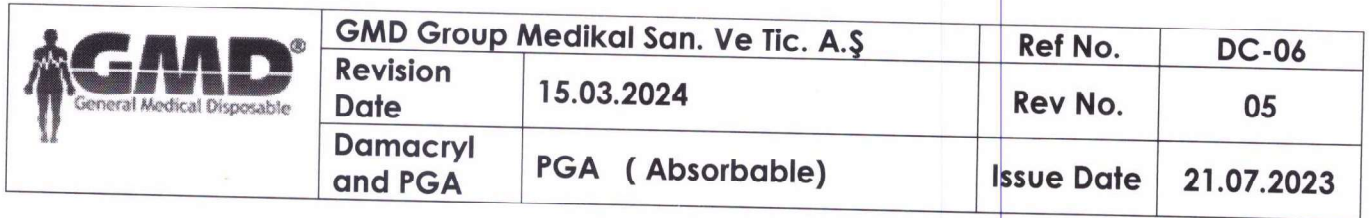
05

Issue Date

21.07.2023

DC40HR26-100	C397	8684154209599	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 4-0 (VIOLET) 26mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC40HR40	C398	8684154209605	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 40mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC50DS12-45	C399	8684154209612	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 5-0 (VIOLET) 12mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC50DS15	C400	8684154209629	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 15mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC50HR15	C401	8684154209636	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 15mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC50HS15	C402	8684154209643	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 15mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC50HR27	C403	8684154209650	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 27mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC60HR12	C404	8684154209667	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (VIOLET) 12mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC00-1X360	C405	8684154214258	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 360cm USP SIZE 0 (VIOLET) WITHOUT NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC00-1X400	C406	8684154214265	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 400cm USP SIZE 0 (VIOLET) WITHOUT NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC01-1X360	C407	8684154214272	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 360cm USP SIZE 1 (VIOLET) WITHOUT NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC02HRH50	C408	8684154214289	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (VIOLET) 50mm 1/2 CIRCLE TAPER POINT (HEAVY) NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC02HR37	C409	8684154214296	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (VIOLET) 37mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC02HRH37-90	C410	8684154214302	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2 (VIOLET) 37mm 1/2 CIRCLE TAPER POINT (HEAVY) NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC00-2X70	C411	8684154214319	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 2PCS X 70cm USP SIZE 0 (VIOLET) WITHOUT NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC03-1X360	C412	8684154214326	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 360cm USP SIZE 3 (VIOLET) WITHOUT NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60

GMD GROUP MEDİKAL
SANAYİ VE TİCARİET ANONİM ŞİRKETİ
TÜRKİYE, İSTANBUL, BEŞİKTAŞ, MAHALLE İSİ DOĞU SOSYAL
BAŞAKŞEHİR, İSTANBUL KAT: 1 NO:7
İKİTELLİ YOLU 34094 161 6679



MED GROUP MEDİKAL
 KAHVE TİCARİTİ MONTE SİRKETİ
 İZMİR OSK. MAHALLESİ İSĐOK SOKYAL
 LWS 1 SOYAK B. KAT: 1 NO:7
 BAŞAKŞEHİR İSTANBUL TÜRKİYE
 İKİLLİ V.D.: 484 161 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

DC30HS20	C428	8684154208271	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 20mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC30HS16	C429	8684154208288	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 16mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC50HS16	C430	8684154208295	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 16mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC50HS20	C431	8684154208301	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 20mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC03HR48	C432	8684154208400	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3 (VIOLET) 48mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC30HR26-D	C433	8684154208554	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 26mm 1/2 CIRCLE ROUND BODY / T.P DOUBLE NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC50DSPR19	C434	8684154208868	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 19mm 3/8 CIRCLE REVERSE CUTTING (PRIME POINT) NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC40DSPR19	C435	8684154208875	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 19mm 3/8 CIRCLE REVERSE CUTTING (PRIME POINT) NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC30DSPR25	C436	8684154208882	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 25mm 3/8 CIRCLE REVERSE CUTTING (PRIME POINT) NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC50HR26-90	C437	8684154208103	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 5-0 (VIOLET) 26mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC00HC26	C438	8684154214739	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 26mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC20HC26	C439	8684154214760	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 26mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC30HC16	C440	8684154214777	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 16mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60
DC30HC20	C441	8684154214784	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 20mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	GMD	DAMACRYL	13908- Polyglycolic acid Suture	Class III	60

GMD GROUP MEDİKAL
 ANA VE TİCARİT ANONİM ŞİRKETİ
 KİMLİĞİ: 25.04.2013
 SİSİ: 25.04.2013
 İZMİR 2. SOYAK BLOK KAT: 1 NO: 7
 İZMİR / İZMİR
 İZMİR V.D.: 484 661 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

DC50HC20	C442	8684154214791	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 20mm 1/2 CIRCLE NORMAL CUTTING EDGE NEEDLE	GMD	DAMACRYL	13908-Polyglycolic acid Suture	Class III	60
DC50HR16-D	C443	8684154214913	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 16mm 1/2 CIRCLE ROUND BODY DOUBLE NEEDLE	GMD	DAMACRYL	13908-Polyglycolic acid Suture	Class III	60
DC20-7X75	C444	8684154214944	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 7PCS X 75cm USP SIZE 2-0 (VIOLET) WITHOUT NEEDLE	GMD	DAMACRYL	13908-Polyglycolic acid Suture	Class III	60
DC02HRT45	C445	8684154215019	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (VIOLET) 45mm 1/2 CIRCLE TAPER CUT NEEDLE	GMD	DAMACRYL	13908-Polyglycolic acid Suture	Class III	60
DC01HR31	C446	8684154215026	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 31mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	GMD	DAMACRYL	13908-Polyglycolic acid Suture	Class III	60
DC00HR31	C447	8684154215033	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 31mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	GMD	DAMACRYL	13908-Polyglycolic acid Suture	Class III	60
DC40-10X75	C448	8684154215842	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 10PCS X 75cm USP SIZE 4-0 (VIOLET) WITHOUT NEEDLE	GMD	DAMACRYL	13908-Polyglycolic acid Suture	Class III	60
DC50HR19	C449	8684154215859	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 19mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	GMD	DAMACRYL	13908-Polyglycolic acid Suture	Class III	60
DC01HS35	C450	8684154215927	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 35mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	GMD	DAMACRYL	13908-Polyglycolic acid Suture	Class III	60
DC30HS30	C451	8684154215934	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 30mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	GMD	DAMACRYL	13908-Polyglycolic acid Suture	Class III	60
DC60DS10	C452	8684154216078	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (VIOLET) 10mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	GMD	DAMACRYL	13908-Polyglycolic acid Suture	Class III	60
DC30DS23	C453	8684154216085	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 23mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	GMD	DAMACRYL	13908-Polyglycolic acid Suture	Class III	60
DC20DS22	C454	8684154216092	DAMACRYL: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 22mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	GMD	DAMACRYL	13908-Polyglycolic acid Suture	Class III	60
JC0M40	J001	8681677072976	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 40mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC1M40	J002	8681677072983	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 40mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC1M30	J003	8681677072990	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 30mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60

GMD GROUP MEDİKAL
 SANAYİ VE TİCARET A.Ş.
 İKİTELLİ OSB, MAHALLESİ, SİRKETİ
 TLEK 2. SOKAK 6. BLOK KAT: 1 NO: 7
 BAŞAKŞEHİR - İSTANBUL - TÜRKİYE
 İKİTELLİ V.D. 484 161 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

JC02M40	J004	8681677073003	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (VIOLET) 40mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC0M45	J005	8681677073010	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 45mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC1M45	J006	8681677073027	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 45mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC02M50	J007	8681677073034	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (VIOLET) 50mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC2M26	J008	8681677073041	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 26mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC2M20	J009	8681677073058	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 20mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC3M16	J010	8681677073065	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 16mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC3M20	J011	8681677073072	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 20mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC4M16	J012	8681677073089	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 16mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC4M12	J013	8681677073096	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 12mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC0K40	J030	8681677073690	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC02K40	J031	8681677073706	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (VIOLET) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC6K13	J044	8681677076554	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (VIOLET) 13mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC3K26	J048	8681677074901	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC2K26	J049	8681677074918	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC3M26	J050	8681677074925	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 26mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60

GMD GROUP MEDİKAL
 SANATİ VE TİCARİET ANONİM ŞİRKETİ
 İKİTELLİ ÜSB. MAHALLESİ İÇİŞİK SOSYAL
 İKİTELLİ ÜSB. 2. SOKAK B. İKİTELLİ KAT: NO:7
 BEŞİKŞEHİR / İSTANBUL / TÜRKİYE
 İKİTELLİ V.D.: 484 161 6579

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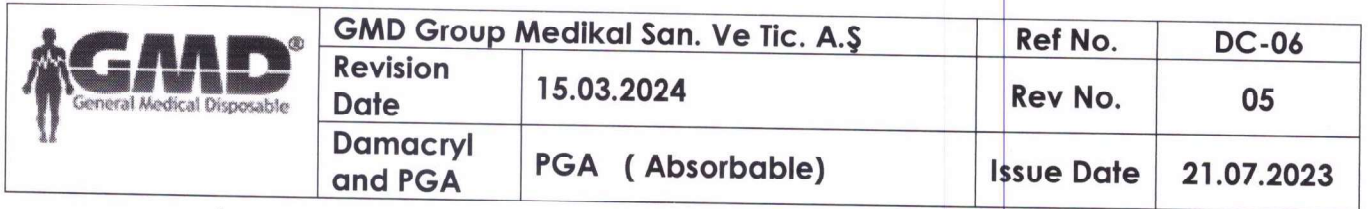
JC4M20	J051	8681677074932	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 20mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC1K40	J052	8681677074949	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JCOM50	J053	8681677074970	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 50mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC2M40	J056	8681677075083	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 40mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC3M30	J057	8681677075090	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 30mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC6M13	J058	8681677075106	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (VIOLET) 13mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC1K50	J059	8681677075113	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 50mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC4M26	J071	8681677075250	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 26mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC6M16	J072	8681677075267	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (VIOLET) 16mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JCOK50	J080	8681677075120	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 50mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JCOM35	J083	8681677075274	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 35mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JCOM48	J096	8681677075427	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 48mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC2M30	J099	8681677075441	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 30mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC5K16	J100	8681677075458	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC5M16	J101	8681677075465	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 16mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC4K20	J102	8681677075472	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60

GMD GROUP MEDİKAL
 SANAYİ VE TİCARİT ANONİM ŞİRKETİ
 İKİTELLİ OSB, MARMARİSİSİDOK SOSYAL
 TESİS 2 BÖLGE, BLOK KAT:1 NO:7
 BAŞAKŞEHİR - İSTANBUL - TÜRKİYE
 İKİTELLİ V.D.: 484 161 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

JC2SK60	J113	8681677076103	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 60mm STRAIGHT REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC2K30	J114	8681677076110	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC1M48-100	J115	8681677076127	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 1 (VIOLET) 48mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC1M50-100	J116	8681677076134	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 1 (VIOLET) 50mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC4K16	J117	8681677076141	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC1K30	J119	8681677076318	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC02M48	J120	8681677076387	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (VIOLET) 48mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC1M48	J125	8681677076400	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 48mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC3SK60	J140	8681677076981	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 60mm STRAIGHT REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC2M40-90	J149	8681677077506	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (VIOLET) 40mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC3K30	J150	8681677077513	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC1M40-90	J151	8681677077520	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (VIOLET) 40mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC1M48-90	J155	8681677077568	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (VIOLET) 48mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC1K45	J158	8681677077599	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 45mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC1K48	J159	8681677077605	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 48mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC02M45	J161	8681677077629	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (VIOLET) 45mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60

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S&J	13908- Polyglycolic acid Suture	Class III	60
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	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

JC00HR40-100	J276	8684154204037	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 0 (VIOLET) 40mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC40DS25	J277	8684154204044	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 25mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC40HR25	J278	8684154204051	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 25mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC01HR35	J279	8684154204068	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 35mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC20HR48	J291	8684154204181	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 48mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC01HR45-100	J292	8684154204198	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 1 (VIOLET) 45mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC01HR40-100	J293	8684154204204	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 1 (VIOLET) 40mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC20HR45	J295	8684154204655	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 45mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC40DS26	J296	8684154204662	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60
JC01HR27	J297	8684154204679	S&J: PGA BRAIDED ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 27mm 1/2 CIRCLE ROUND BODY / T.P NEEDLE	S&J	S&J	13908-Polyglycolic acid Suture	Class III	60

Product specifications

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 BAŞAKŞEHİR - İSTANBUL - TÜRKİYE
 İKİTELLİ V.D.: 484 181 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

Table 1 USP <861> Standard diameter and knot tensile strength

Table 1. Synthetic suture-The average diameter of the strands being measured is within the tolerances prescribed in Table 1 for the respective size. None of the observed measurement is less than the midpoint of the range for the next smaller size or greater than the midpoint of the range for the next larger size.

Table 1. Synthetic Suture.				
USP Size	Metric Size (Gauge No)	Limits on Average Diameter(mm)		Knot-pull Tensile Strength (kgf) (except where otherwise specified) Limit on Average Min
		Min	Max	
12-0	0.01	0.001	0.009	-
11-0	0.1	0.010	0.019	-
10-0	0.2	0.020	0.029	0.025*
9-0	0.3	0.030	0.039	0.050*
8-0	0.4	0.040	0.049	0.07
7-0	0.5	0.050	0.059	0.14
6-0	0.7	0.070	0.089	0.25
5-0	1	0.10	0.149	0.68
4-0	1.5	0.15	0.199	0.95
3-0	2	0.20	0.249	1.77
2-0	3	0.30	0.359	2.68
0	3.5	0.35	0.399	3.90
1	4	0.40	0.499	5.08
2	5	0.50	0.599	6.35
3 and 4	6	0.60	0.699	7.29
5	7	0.70	0.799	-

* The tensile strength of the specified USP size is measured by straight pull.

1.4.1 Components and Raw Materials of product:

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TESİS 2 SOKAKI, BLOK KAT: 3 NO:7
BAŞAKŞEHİR / İSTANBUL / TÜRKİYE
T.C. MİTTELİ V.D.: 484 161 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

Surgical Suture

Surgical Needle

Manufacturer/Supplier	Material
METABIOMED	Polyglycolic Acid (pga),beige (undyed),coated
Kota Ambalaj	Shrinking Cover
Quality Needles Pvt	Stainless Steel
Kemal Kurşun	Aluminium foil with P.E. layer
Anging Kangmingna	Big Over Wrap and Small Over Wrap
Panograf	Boxes

1.5.Accessories Information+

There is no accessories.

1.7.Suitability of Raw Material

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

1.8.Indication ,Contraindication and Adverse Reactions

INDICATIONS

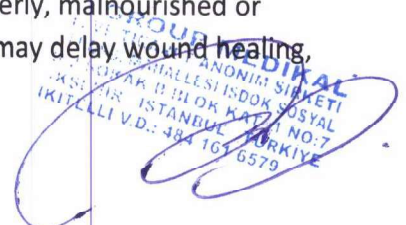
DAMACRYL AND PGA suture is indicated for use in general soft tissue approximation and ligation, including the use in ophthalmic procedures. DAMACRYL AND PGA is not for use in cardiovascular or neurological tissues.

CONTRAINDICATIONS

DAMACRYL AND PGA suture, being absorbable, should not be used where extended approximation of tissue is required.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing,


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	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site.

Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of blood borne pathogens.

1.9. Material Specifications:

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

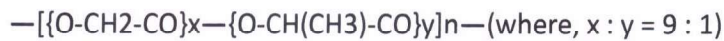
1.9.1.Thread (PGA multifilament,Mepfil-Lac ®)

The following specifications are met:

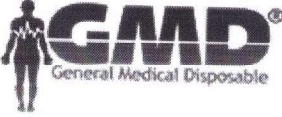
Appearance:

Beige(undyed) colored multifilament braided multifibers according to the size of the strands that meets all the requirements of the European Pharmacopoeia (EP) for Synthetic Absorbable Multifilament Sutures and the requirements of United States Pharmacopoeia (USP) Absorbable Sutures except for a slight oversize in diameter.

Formula of polyglycolic acid:



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TİSİS : ÇOKAK BULVARI NO:7
BAŞAKŞEHİR - İSTANBUL - TÜRKİYE
İKİTİLLİ V.D. 384 161 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

Content of residues:

Monomers ≤ 1.0 w/w %

Catalysts ≤ 100 ppm Heavy

metals ≤ 10 ppm Solvents $\leq$

500ppm

Additives:

Stabilizing agent : none Antioxidizing

agent : none Dyestuffs

Undyed braids : none

Coating

Calcium stearate

$\text{Ca}[\text{O}-\text{CO}-(\text{CH}_2)_{16}-\text{CH}_3]_2$

Content : ≤ 5 w/w %

Physical Specification

Damacryl and PGA 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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Tİ. KİŞ. 7. BLOK KAT : 1 NO:7
BAŞAKŞEHİR İSTANBUL TÜRKİYE
İKİTİLLİ V.D.: 484 161 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

Knot pull tensile strength linear pull tensile strength for non-sterile braid

USP 29 NF24 Page 2050

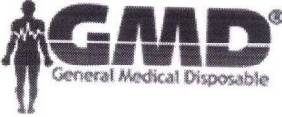
USP Size Min.	Metric Size (Gauge No.) Max.	Limits on Average Diameter (mm)		Knot-Pull Tensile Strength (in kgf) (except where otherwise specified)* Limit on Average Min.	Knot-Pull Tensile Strength (in N) (except where otherwise specified)
		Min.	Max.		
12-0	0.01	0.001	0.009	—	—
11-0	0.1	0.010	0.019	—	—
10-0	0.2	0.020	0.029	0.025*	0.24*
9-0	0.3	0.030	0.039	0.050*	0.49*
8-0	0.4	0.040	0.049	0.07	0.69
7-0	0.5	0.050	0.069	0.14	1.37
6-0	0.7	0.070	0.099	0.25	2.45
5-0	1	0.10	0.149	0.68	6.67
4-0	1.5	0.15	0.199	0.95	9.32
3-0	2	0.20	0.249	1.77	17.4
2-0	3	0.30	0.339	2.68	26.3
0	3.5	0.35	0.399	3.90	38.2
1	4	0.40	0.499	5.08	49.8
2	5	0.50	0.599	6.35	62.3
3 and 4	6	0.60	0.699	7.29	71.5
5	7	0.70	0.799	—	—

* The tensile strength of the specified USP size is measured by straight pull.

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	0.069
	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

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TİSİK 3. KÖKAR K. BLOK KAT : 1 NO:7
RASATSEHİR İSTANBUL / TÜRKİYE
İKİTİLLİ V.D.: 484 161 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

Moisture content : ≤ 400 ppm

Retention ratio of tensile strength

About 75% of the initial strength after two week

1.9.2.NEEDLE:

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

1.9.3. Tipping solution Araldite Standart

Araldite is a low visocisty cyanoacrylate adhesive for assembling medical device. 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.

1.9.4. Specification of primary and secondary packaging material

Primary packaging material is made of Aluminium foil

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

1.10. 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 gastrointestinal, obstetric and gynecologic and urologic surgery.

1.11. Intended User

The device should used by physician and/or surgeons.

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TİSİS ÇOKAK B.İLE, 35000 KOSYAL
BAŞAKŞEHİR İSTANBUL TÜRKİYE
İKTİLLİ V.D.: 484 161 6575

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

1.12. 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.

1.13. Single Use / Reusable

The device is only single-used.

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

1.14. Mechanism of Action / Principles of Operation

DAMACRYL AND PGA sutures elicit minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of DAMACRYL AND PGA sterile, synthetic, absorbable suture occurs by means of hydrolysis, where the polymer degrades to glycolic acid which is subsequently absorbed and metabolized by the body. Absorption begins as a loss of tensile strength without appreciable loss of mass. The material holds approximately 75% of its tensile strength by the end of two weeks and approximately 45% by the third week. The absorption is completed in approximately from 60 to 90 days.

1.15. Biodegradation mechanism of the device

The literature describing the biodegradation mechanism for PGA polyglycolic acid is indicated in the annexes.(Annex-1 , Annex-2, Annex-3, Annex-4)

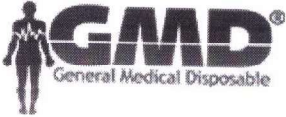
1.16. Biological and Toxicological Evaluation

The following section contains information on the preclinical evaluation of the raw materials and the toxicological and biocompatibility tests on the sterile finished product Damacryl.(TF13 Clinical and Biological Evaluation)

1.17. Biocompatibility Tests of the Raw Materials for Medical Device Damacryl and PGA(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

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	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

endpoints that can be necessary for a biological safety evaluation per ISO 10993-1, based on a risk analysis. Where existing data are adequate, additional testing is not required. (Clinical and Biological Evaluation)

1.18. Manufacturing Process:

Manufacturing is performed at the İkitelli O.S.B İsdök Sanayi Sitesi İsdök Sosyal Tesis Plaza Binasi B Blok No :7-8. 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, are packed into aluminium paper, then packed again 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 an aluminum foil inner envelope (primary packaging) and labeled in ISO 8 Clean Room, but not sealed at this stage.
- This inner aluminum envelope is then placed in an outer envelope (secondary packaging), which is sealed.

One package unit of Damacryl and PGA contains 12 single pouches.

Sterilization

Damacryl and PGA(PGA) sutures are sterilized in-house by EtO. They are then vacuum- dried,

GMD GROUP MEDİKAL
İKİTELLİ O.S.B. MAHALLESİ ANONİM ŞİRKETİ
T.C. SİS 7. BLOK B BLOK İSDÖK SOSYAL
BASAKŞEHİR İSTANBUL KAT: 1 NO: 7
İKİTELLİ V.B.: 484 161 0579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

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 11135:2014. Main routine sterilization parameters are 40 °C %40 Humidity with a gas injection period of 5 hours.

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

Drying

Damacryl and PGA sutures are dried after EtO sterilization. They are vacuum-dried using a vacuum oven (3 hours, 75°C) Then with Nitrogen washing for 12 hours and a final vacuum 5 hours and drying for another 3 hours. At the end of the drying process the aluminium packages are sealed under controlled conditions. The sutures are then boxed, 12 per box and boxes are wrapped by shrinking cover.

Packaging into cartons

Twelve sutures pouches are packed into a carton and labelled. Each carton is polyolefin 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.

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

GMD GROUP MEDİKAL
ANAYI
MİLLİ CİBRİ MAHALLESİ ANONİM ŞİRKETİ
TEŞİS VE BAKIM BİNA KAT: 1 NO: 2
BAŞAKŞEHİR İSTANBUL TÜRKİYE
İKİTELLİ Y.D. 384 161 6579

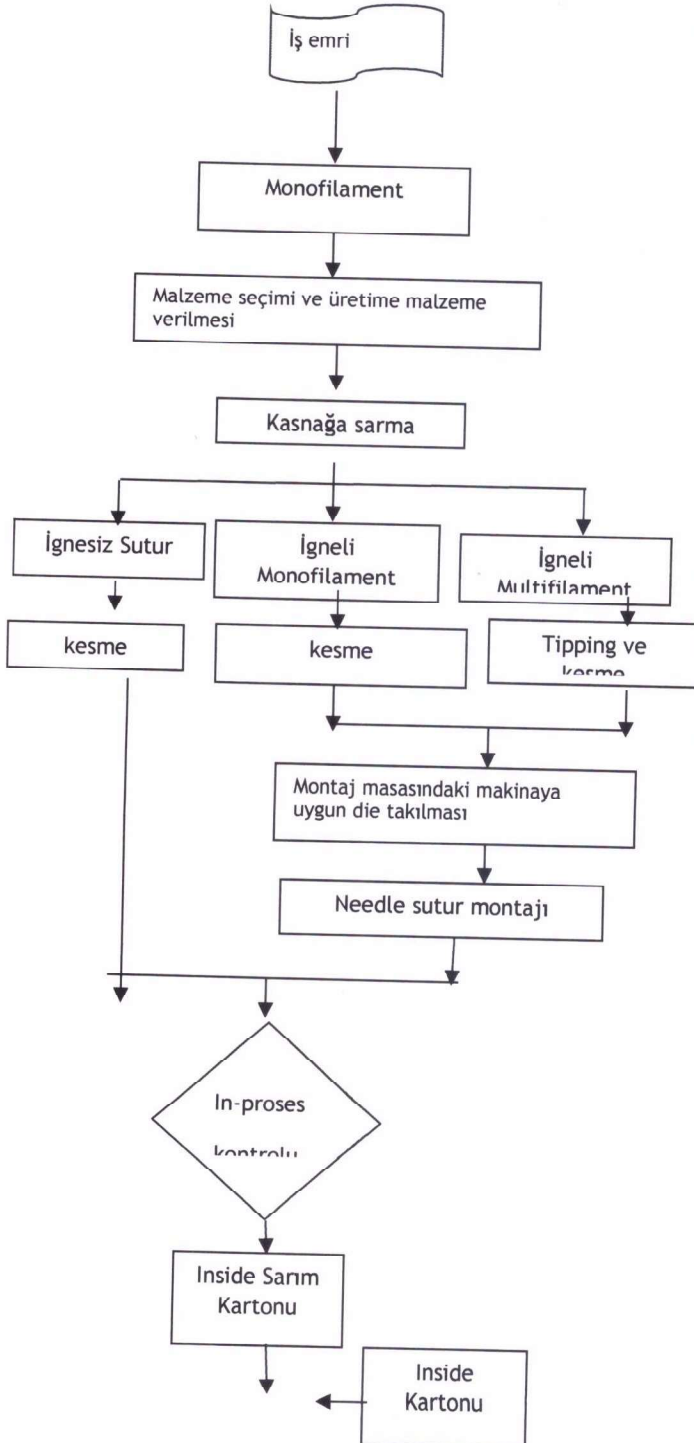
	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

Manufacturing Flow Chart

İŞ AKIŞI

İLGİLİ DOKÜMAN

SORUMLU



UR02001- İş Emri Açma Talimatı

UR02002-İş Emrine Uygun Malzeme Seçimi Talimatı

DP02007-Depoya Malzeme Girişi ve Üretime Malzeme Çıkışı Talimatı

UR02003-Kasnağa Sarma, Kesme ve Makina Çalıştırma Talimatı

UR02006-Die Takma ve Pull-Tester Ayarlama Talimatı

KG02021-In-proses Kontrol Talimatı

UR02007- Needle ve Suturen

Üretim

Üretim Sorumlusu

Depo ve sevkiyat sorumlusu

Üretim Sorumlusu ve Üretim Elemanı

Üretim Sorumlusu

KG Müdürü

Üretim Elemanı

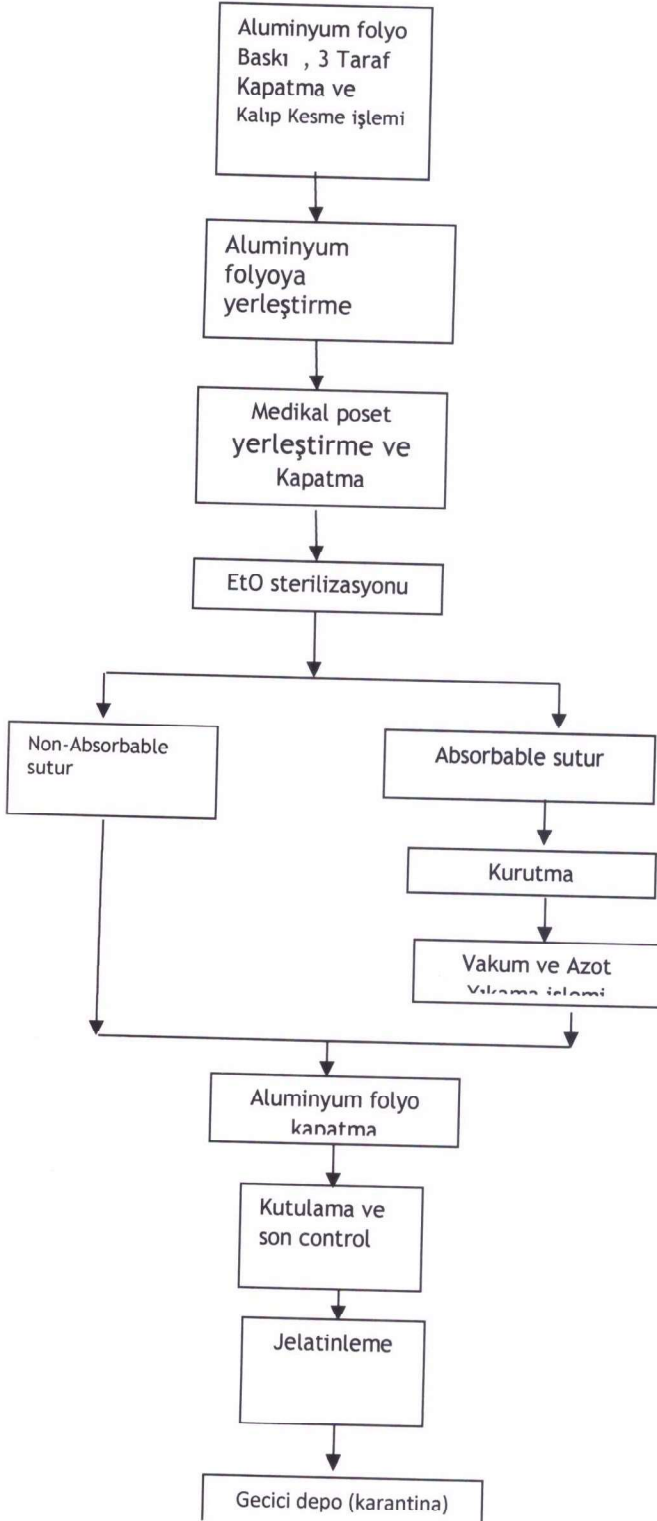
KG Müdürü

KG Müdürü

Üretim Elemanları

GMD GROUP MEDİKAL
SANAYİ VE TİCARİT ANONİM ŞİRKETİ
İKİTELLİ OSB. MAHALLE ANONİM ŞİRKETİ
TESİSİ : GÖKAK HÜYKELİSOKAK SOSYAL
BAŞAKŞEHİR - İSTANBUL KAT : 1 NO:7
İKİTELLİ V.D. 484 161 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023



UR02010 - Suturlerin
Alüminyum Folyoya Koyma
Talimatı

Üretim
Elemanı

UR02004- Büyük ve Küçük
Paket Kapatma Makinası
Çalıştırma Talimatı

Üretim
Elemanı

UR02060 - Sterilizasyon
Cihazı Kullanma Talimatı

Üretim
Sorumlusu

UR02044 - 75 C lik Etuv
Kullanma Talimatı

Üretim
Sorumlusu

UR02056 Absorbable
(Absorbable) Suturlerin
Alüminyum Folyo Tek
Tarf Kapatma Talimatı

Üretim
Elemanı

Üretim
Elemanı

Üretim
Elemanı

Üretim
Elemanı

UR02055 Emilemeyen
(Non-Absorbable)
Suturlerin Alüminyum
Folyo Kapatma
Talimatı

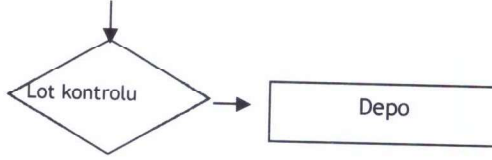
Üretim
Elemanı

UR02033_Kalıp kesme
makinesi kullanma talimatı

UR02004- Büyük ve Küçük

GMD GROUP MEDİKAL
SANAYİ VE TİCARET ANONİM ŞİRKETİ
İKİTELLİ OSB, MAHALLESTİSİBOK SOSYAL
TESİS 2 SOYAK 8 BLOK KAT : 1 NO:7
BAŞAKŞEHİR İSTANBUL TÜRKİYE
İKİTELLİ V.D.: 484 406579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023



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

1.19. Product and Test Specifications:

The Damacryl and PGA® range of sutures started to successfully produced and extensively used in 2016(June)

The following tests are specified as final batch release controls according to USP 0:

Table: Test specifications and Lot results

Pilot Production

Test Parameter	Method	Lot 16C01 DR0M36	
		Limit	Result
Needle Attachment	USP 0	15,0	28,4
Validation1 Sterility Test	USP 0	Sterile	Sterile

Test Parameter	Method	Lot 16C01 DR1M30	
		Limit	Result
Needle Attachment	USP 0	1,80	5,613
Sterility Test	USP 0	Sterile	Sterile
Water content(moisture)		0.25	0.15

Validation 2

GMD GROUP MEDİKAL
SANAYİ VE TİCARET ANONİM ŞİRKETİ
İKİTELLİ/ÖSB. MAHALLESİ/SDOK SOKAL
TELİSİ/ SOKAK B BLOK KAT / NO:7
BAŞAKŞEHİR / İSTANBUL / TÜRKİYE
İKİTELLİ VD. 484 161 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

Parameter	Method	Lot 16C01 DR0M36	
		Limit	Result
Needle Attachment	USP 0	1,80	6,827
Sterility Test	USP 0	Sterile	Sterile
Water content(moist ure)		0.25	0.13

GMD GROUP MEDİKAL
 SANAYİ VE TİCARET ANONİM ŞİRKETİ
 İKİTELLİÇİME MAHALLESİ İSODOK SOSYAL
 TENİS 2 SOKAKI 4. BLOK KAT : 1 NO:7
 PAŞAİÇİMEHİR / İSTANBUL / TÜRKİYE
 İKİTELLİ T.C. 484 101 0579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

Sterility Test	USP 0	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile
Water content(moist ure)		0.25	0.15	0.25	0.15	0.25	0.15

The test reports of PGA lots given on the above table are given on TF11 Test reports

1.20. Stability/Aging Test and Product Life Time :

The relevant tests and reports are given on TF11 Test Reports

1.21. Product Tests(Performance) :

The relevant tests and reports are given on TF11 Test Reports

1.22. The Product Classification

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

Rule 8:

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

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

GMD GROUP MEDİKAL
SANAYİ VE TİCARET ANONİM ŞİRKETİ
İKİTELLİ ÖSD. MAHALLESİ İZMİR SOKAK
TİSİS 4 SOKAK B BLOK KAT :1 NO:7
BAŞARİŞEHİR İSTANBUL TÜRKİYE
İKİTELLİ V.D.: 304 161 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

1.23. Clinical Evaluation :

For the clinical evaluation of GMD literature route of MEDDEV 2.7.1Rev.4 has been selected. Clinical Evaluation is given DC03 of this technical file.

1.24. Decleration 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 DC 12 of this technical file.

1.25. 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 .

1.26. 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 DC 13 of this technical file.

1.27. 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 DC 02 of this technical file.

1.28. Risk Analyses

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

GMD GROUP MEDİKAL
İZNAYI VE TİCARİT ANONİM ŞİRKETİ
İKİTİLLİ OSB/MAHALLE İSOK SOSYAL
TİSİS 2 SOKAK B BLOK KAT:1 NO:7
BAŞAKŞEHİR İSTANBUL TÜRKİYE
İKİTİLLİ V.D.: 484 161 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

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 dc 11 of this technical file.

1.29. Conformity Assessment Procedure:

Damacryl and PGAManufactured 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.

GMD GROUP MEDİKAL
 SANAYİ VE TİCARET ANONİM ŞİRKETİ
 İKİTELLİ OSU MAHALLESİ / 2. SOYAL
 TESİS 2 SOKAK II KAT : NO:7
 BAŞAKŞİHİR İSTANBUL TÜRKİYE
 İKİTELLİ V.D. : 484 161 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

Biocompatibility Test Matrix

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

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

Product	Classification	Required Tests
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GMD GROUP MEDICAL
SANAYİ VE TİCARET ANONİM ŞİRKETİ
İKİTELLİ OSB, MAHAYILIM ISDOK BÖŞYAL
TESİS 2 BÖKAK 11. BÖKAK KAT:1 NO:7
BAŞAKŞEHİR - İSTANBUL - TÜRKİYE
İKİTELLİ V.D. 484 161 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

Damacryl	Implant Devices Tissue/Bone C-Permanent	• Cytotoxicity • Sensitization • Irritation • Acute Systemic Toxicity • Subchronic Toxicity • Genotoxicity • Implantation
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The following evaluation is taken by NAMSA, CA. U.S.A.

- Cytotoxicity study using the ISO elution method
- In vitro hemolysis study
- ISO sensitization study in the guinea pig
- ISO acute systemic toxicity study in the mouse
- ISO acute intracutaneous reactivity study in the rabbit
- ISO rabbit pyrogen study
- ISO muscle implantation study in the rabbit (4 weeks)
- ISO muscle implantation study in the rabbit (26 weeks)

Genotoxicity:bacterial reverse mutation study.

The results of the biocompatibility tests on the PGA absorbable braid demonstrate the excellent biocompatibility of the PGA material and also demonstrate that the ETO sterilization does not have any negative effects on the polymer material

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

All related test reports, supplier data and related documentation with this section are given on Test Reports of this technical file.

1.31. Biodegradation for Medical Device Damacryl.

Using the polyglycolide and poly(L-lactide) properties as a starting point, it is possible to copolymerize the two monomers to extend the range of homopolymer properties. Copolymers of glycolide with both L-lactide and DL-lactide have been developed for both device and drug delivery applications

GMD GROUP MEDİKAL
 SANAYİ VE TİCARET ANONİM ŞİRKETİ
 İKİTELLİ OSB. MAHALLESİ İSODOK SOSYAL
 TESİS 2 SOKAK D BLOK KAT : NO:7
 BAŞAKŞEHİR İSTANBUL TÜRKİYE
 İKİTELLİ V.D.: 484 161 0579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

Sterility test and absorbability study in rats by Korea Testing & Research Institute

This study was performed to evaluate sterility and absorbability in rat.

1.32. Planned Design Change

No design changes are planned. If a change is required, it must be made in accordance with the GE01021 Release Management provisions. The notified body is notified when there is a change to comply with the requirements of MDCG 2020-3 and MDR Article 120

1.33. Sale Information for DAMACRYL and PGA

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 2018 sale informations has been presented below;

DAMACRYL	Tayland	13	
	Azerbaijan	1937	
	Czech Republic	115	
	Egypt	15040	
	Iraq	33154	
	Jordan	38	
	Libya	3397	
	Palestine	2195	
	Türkiye	73191	
	Vietnam	160	
	Somali	1425	
	Kuveyt	800	
	Almanya	632	
	Yemen	14618	
	Dubai	778	
	Rusya	40	
	Romanya	7773	
	Fildişi Sahili	16	
	Kosova	2165	
	Kenya	22	
	Lübnan	1961	
	KARASIK	28	
	Nepal	100	
DAMACRYL Total		159598	

GMD GROUP MEDİKAL
SANAYİ VE TİCARET ANONİM ŞİRKETİ
İKİTELLİ OSB, MAHALLESİ/İSBÜK SOSYAL
TESİS 2 SOKAK B BLOK KAT : 1 NO : 1
BAŞAKŞEHİR - İSTANBUL - TÜRKİYE
İKİTELLİ V.D. 484 161 6579

	GMD Group Medikal San. Ve Tic. A.Ş		Ref No.	DC-06
	Revision Date	15.03.2024	Rev No.	05
	Damacryl and PGA	PGA (Absorbable)	Issue Date	21.07.2023

Rev. History

Rev.0 08.07.2016	Initial publish
Rev.1 17.08.2018	Added Product Model Names
Rev.2 25.10.2018	Items: Intended use of the product, 1Intended user, Patient Population, Design Change, Sale Information have been changed and mentioned inthe document by highlight.
Rev.3 12.06.2019	Title update and updated some information
Rev 04 10.05.2023	Revisions were made according to notified body nonconformities.

GMD GROUP MEDİKAL
 SANAYİ VE TİCARET ANONİM ŞİRKETİ
 İKİTELLİ OSB. MAHALLESİ İSĐOK SOSYAL
 TESİS 2. SOKAK BLOK KAT :1 NO:7
 BAŞAKŞEHİR İSTANBUL TÜRKİYE
 İKİTELLİ V.D.: 484 161 6579