



C E R T I F I C A T E

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name	: Tolmed Medikal Tekstil San. ve Tic. Ltd. Şti.
Company Address	: Huzur Mahallesi 1218 Cad. No:5B Çankaya ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Non Sterile Screw and Rod System - Class IIb Sterile Cervical ve Lumbar PEEK Cages - Class IIb Non Sterile Corpectomy Cages - Class IIb Sterile Cervical Mobile Disc Prosthesis - Class IIb Non Sterile Plate System - Class IIb Non Sterile Occipital Plate - Class IIb Non Sterile Posterior Screw and Rod System - Class IIb
GMDN	: 61325, 38161, 43084 Product Types are attached.
Certificate Number	: M.2016.106.6914
Report Number	: MD.3145.YB
Initial Assessment Date	: 08.06.2016
Registration Date	: 04.08.2016
Recertification Assessment Date	: 02.08.2019
Reissue Date / No	: 13.04.2020/01
Revision Date /No	: -
Expiry Date	: 27.05.2024



UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev.ce is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

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This document containing 5 (five) pages is the Annex of the Certificate with the number M.2016.106.6914 and with the registration date of 04.08.2016 and with the re-issue date 13.04.2020 issued for "Tolmed Medikal Tekstil San. ve Tic. Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

STERILE SUPERMED LUMBAR FUSION PEAK CAGE	22x6 MM, 22x7 MM, 22x8 MM, 22x9 MM, 22x10 MM, 22x11 MM, 22x12 MM, 24x6 MM, 24x7 MM, 24x8 MM, 24x9 MM, 24x10 MM, 24x11 MM, 24x12 MM	SLCD2206, SLCD2207, SLCD2208, SLCD2209, SLCD2210, SLCD2211, SLCD2212, SLCD2406, SLCD2407, SLCD2408, SLCD2409, SLCD2410, SLCD2411, SLCD2412	38161
STERILE SUPERMED LUMBAR FUSION PEAK ANGLED CAGE	22x6 MM, 22x7 MM, 22x8 MM, 22x9 MM, 22x10 MM, 22x11 MM, 22x12 MM, 22x14 MM, 22x16 MM, 24x6 MM, 24x7 MM, 24x8 MM, 24x9 MM, 24x10 MM, 24x11 MM, 24x12 MM	SLCA2206, SLCA2207, SLCA2208, SLCA2209, SLCA2210, SLCA2211, SLCA2212, SLCA2214, SLCA2216, SLCA2406, SLCA2407, SLCA2408, SLCA2409, SLCA2410, SLCA2411, SLCA2412	38161
STERILE SUPERMED MINIMAL INVAZIVE TLIF CAGE	24x12x7, 24x12x8, 24x12x9, 24x12x10, 24x12x11, 24x12x12	SAC1207, SAC1208, SAC1209, SAC1210, SAC1211, SAC1212	38161
STERILE SUPERMED HIGH FLEX EXPENDABLE LUMBAR PEAK CAGE	24x10x7, 24x10x8, 24x10x9, 24x10x10, 24x10x11, 24x10x12	SEPC1007, SEPC1008, SEPC1009, SEPC1010, SEPC1011, SEPC1012	38161
STERILE SUPERMED TLIF PEAK CAGE	24x10x7, 24x10x9, 24x10x11, 24x10x13, 28x10x7, 28x10x9, 28x10x11, 28x10x13, 32x10x7, 32x10x9, 32x10x11, 32x10x13	SBC2407, SBC2409, SBC2411, SBC2413, SBC2807, SBC2809, SBC2811, SBC2813, SBC3207, SBC3209, SBC3211, SBC3213	38161
STERILE SUPERMED TLIF PEAK CAGE 4 ANGLED	24x10x7, 24x10x9, 24x10x11, 24x10x13, 28x10x7, 28x10x9, 28x10x11, 27x10x13, 32x10x7, 32x10x9, 32x10x11, 32x10x13	SBCA2407, SBCA2409, SBCA2411, SBCA2413, SBCA2807, SBCA2809, SBCA2811, SBCA2813, SBCA3207, SBCA3209, SBCA3211, SBCA3213	38161
STERILE SUPERMED HIGH FLEX EXPENDABLE TLIF PEAK CAGE	24x10x7, 24x10x9, 24x10x11, 24x10x13, 28x10x7, 28x10x9, 28x10x11, 27x10x13, 32x10x7, 32x10x9, 32x10x11, 32x10x13	SEB2407, SEB2409, SEB2411, SEB2413, SEB2807, SEB2809, SEB2811, SEB2813, SEB3207, SEB3209, SEB3211, SEB3213	38161
STERILE SUPERMED HIGH FLEXIBLE OPENABLE LUMBAR PEAK CAGE	24x10x7, 24x10x8, 24x10x9, 24x10x10, 24x10x11, 24x10x12	SYAL1007, SYAL1008, SYAL1009, SYAL1010, SYAL1011, SYAL1012	38161
SUPERMED CERVICAL ANTERIOR PLATE	12 mm, 14 mm, 16 mm, 18 mm, 20 mm, 22 mm, 24 mm, 26 mm, 28 mm, 30 mm, 32 mm, 34 mm, 37 mm, 39mm, 40 mm, 42mm, 43 mm, 45mm, 46 mm, 48 mm, 51 mm, 54 mm, 57 mm, 60 mm, 63 mm, 64mm, 66 mm, 68mm, 69 mm, 72 mm, 76 mm, 80 mm, 84 mm, 88 mm, 92 mm	CAP12, CAP14, CAP16, CAP18, CAP20, CAP22, CAP24, CAP26, CAP28, CAP30, CAP32, CAP34, CAP37, CAP39, CAP40, CAP42, CAP43, CAP45, CAP46, CAP48, CAP51, CAP54, CAP57, CAP60, CAP63, CAP64, CAP66, CAP68, CAP69, CAP72, CAP76, CAP80, CAP84, CAP88, CAP92	61325
SUPERMED CERVICAL ANTERIOR PLATE SCREW	4.0x10, 4.0x12, 4.0x14, 4.0x16, 4.0x18, 4.0x20, 4.5x10, 4.5x12, 4.5x14, 4.5x16, 4.5x18, 4.5x20	CAPS4010, CAPS4012, CAPS4014, CAPS4016, CAPS4018, CAPS4020, CAPS4510, CAPS4512, CAPS4514, CAPS4516, CAPS4518, CAPS4520	61325
SUPERMED CERVICAL ANTERIOR PLATE REVISION SCREW	4.0x10, 4.0x12, 4.0x14, 4.0x16, 4.0x18, 4.0x20, 4.5x10, 4.5x12, 4.5x14, 4.5x16, 4.5x18, 4.5x20	CAPSR4010, CAPSR4012, CAPSR4014, CAPSR4016, CAPSR4018, CAPSR4020, CAPSR4510, CAPSR4512, CAPSR4514, CAPSR4516, CAPSR4518, CAPSR4520	61325
SUPERMED POLYAXIAL TYPE II COATED UNIQUE SCREW	3.5x25 MM, 3.5x30 MM, 3.5x35 MM, 3.5x40 MM, 3.5x45 MM, 4.0x25 MM, 4.0x30 MM, 4.0x35 MM, 4.0x40 MM, 4.0x45 MM, 4.0x50 MM, 4.5x25 MM, 4.5x30 MM, 4.5x35 MM, 4.5x40 MM, 4.5x45 MM, 4.5x50 MM, 5.0x25 MM, 5.0x30 MM, 5.0x35 MM, 5.0x40 MM, 5.0x45 MM, 5.0x50 MM, 5.5x25 MM, 5.5x30 MM, 5.5x35 MM, 5.5x40 MM, 5.5x45 MM, 5.5x50 MM, 5.5x55 MM, 6.0x25 MM, 6.0x30 MM, 6.0x35 MM, 6.0x40 MM, 6.0x45 MM, 6.0x50 MM, 6.0x55 MM, 6.0x60 MM, 6.2x25 MM, 6.2x30 MM, 6.2x35 MM, 6.2x40 MM, 6.2x45 MM, 6.2x50 MM, 6.2x55 MM, 6.2x60 MM, 6.5x25 MM, 6.5x30 MM, 6.5x35 MM, 6.5x40 MM, 6.5x45 MM, 6.5x50 MM, 6.5x55 MM, 7.0x25 MM, 7.0x30 MM, 7.0x35 MM, 7.0x40 MM, 7.0x45 MM, 7.0x50 MM, 7.0x55 MM, 7.5x25 MM, 7.5x30 MM, 7.5x35 MM, 7.5x40 MM, 7.5x45 MM, 7.5x50 MM, 7.5x55 MM, 7.5x60 MM, 8.0x30 MM, 8.0x35 MM, 8.0x40 MM, 8.0x45 MM, 8.0x50 MM, 8.0x55 MM, 8.0x60 MM, 8.0x65 MM, 8.0x70 MM, 8.0x80 MM, 8.0x90 MM, 8.0x100 MM	PASE3525, PASE3530, PASE3535, PASE3540, PASE3545, PASE4025, PASE4030, PASE4035, PASE4040, PASE4045, PASE4050, PASE4525, PASE4530, PASE4535, PASE4540, PASE4545, PASE5025, PASE5030, PASE5035, PASE5040, PASE5045, PASE5050, PASE5525, PASE5530, PASE5535, PASE5540, PASE5545, PASE5550, PASE6025, PASE6030, PASE6035, PASE6040, PASE6045, PASE6050, PASE6055, PASE6060, PASE6225, PASE6230, PASE6235, PASE6240, PASE6245, PASE6250, PASE6255, PASE6260, PASE6525, PASE6530, PASE6535, PASE6540, PASE6545, PASE6550, PASE6555, PASE6560, PASE6565, PASE6570, PASE6575, PASE6580, PASE6585, PASE6590, PASE6595, PASE7025, PASE7030, PASE7035, PASE7040, PASE7045, PASE7050, PASE7055, PASE7060, PASE7525, PASE7530, PASE7535, PASE7540, PASE7545, PASE7550, PASE7555, PASE7560, PASE8030, PASE8035, PASE8040, PASE8045, PASE8050, PASE8055, PASE8060, PASE8065, PASE8070, PASE8080, PASE8090, PASE80100	61325
SUPERMED POLYAXIAL TYPE II COATED UNIQUE REDUCTION SCREW	3.5x25 MM, 3.5x30 MM, 3.5x35 MM, 3.5x40 MM, 3.5x45 MM, 4.0x25 MM, 4.0x30 MM, 4.0x35 MM, 4.0x40 MM, 4.0x45 MM, 4.0x50 MM, 4.5x25 MM, 4.5x30 MM, 4.5x35 MM, 4.5x40 MM, 4.5x45 MM, 4.5x50 MM, 5.0x25 MM, 5.0x30 MM, 5.0x35 MM, 5.0x40 MM, 5.0x45 MM, 5.0x50 MM, 5.5x25 MM, 5.5x30 MM, 5.5x35 MM, 5.5x40 MM, 5.5x45 MM, 5.5x50 MM, 5.5x55 MM, 6.0x25 MM, 6.0x30 MM, 6.0x35 MM, 6.0x40 MM, 6.0x45 MM, 6.0x50 MM, 6.0x55 MM, 6.0x60 MM, 6.2x25 MM, 6.2x30 MM, 6.2x35 MM, 6.2x40 MM, 6.2x45 MM, 6.2x50 MM, 6.2x55 MM, 6.2x60 MM, 6.5x25 MM, 6.5x30 MM, 6.5x35 MM, 6.5x40 MM, 6.5x45 MM, 6.5x50 MM, 6.5x55 MM, 7.0x25 MM, 7.0x30 MM, 7.0x35 MM, 7.0x40 MM, 7.0x45 MM, 7.0x50 MM, 7.0x55 MM, 7.5x25 MM, 7.5x30 MM, 7.5x35 MM, 7.5x40 MM, 7.5x45 MM, 7.5x50 MM, 7.5x55 MM, 7.5x60 MM, 8.0x30 MM, 8.0x35 MM, 8.0x40 MM, 8.0x45 MM, 8.0x50 MM, 8.0x55 MM, 8.0x60 MM, 8.0x65 MM, 8.0x70 MM, 8.0x80 MM, 8.0x90 MM, 8.0x100 MM	PASEL3525, PASEL3530, PASEL3535, PASEL3540, PASEL3545, PASEL4025, PASEL4030, PASEL4035, PASEL4040, PASEL4045, PASEL4050, PASEL4525, PASEL4530, PASEL4535, PASEL4540, PASEL4545, PASEL5025, PASEL5030, PASEL5035, PASEL5040, PASEL5045, PASEL5050, PASEL5525, PASEL5530, PASEL5535, PASEL5540, PASEL5545, PASEL5550, PASEL6025, PASEL6030, PASEL6035, PASEL6040, PASEL6045, PASEL6050, PASEL6055, PASEL6060, PASEL6225, PASEL6230, PASEL6235, PASEL6240, PASEL6245, PASEL6250, PASEL6255, PASEL6260, PASEL6525, PASEL6530, PASEL6535, PASEL6540, PASEL6545, PASEL6550, PASEL6555, PASEL6560, PASEL6565, PASEL6570, PASEL6575, PASEL6580, PASEL6585, PASEL6590, PASEL6595, PASEL7025, PASEL7030, PASEL7035, PASEL7040, PASEL7045, PASEL7050, PASEL7055, PASEL7060, PASEL7525, PASEL7530, PASEL7535, PASEL7540, PASEL7545, PASEL7550, PASEL7555, PASEL7560, PASEL8030, PASEL8035, PASEL8040, PASEL8045, PASEL8050, PASEL8055, PASEL8060, PASEL8065, PASEL8070, PASEL8080, PASEL8090, PASEL80100	61325
SUPERMED SACROILIAC SCREW TITANIUM	6.0x35mm 6.0x40mm 6.0x45mm 6.0x50mm 6.0x55mm 7.0x40mm 7.0x45mm 7.0x50mm 7.0x55mm 7.0x60mm 7.0x65mm 7.0x70mm 7.0x75mm 7.0x80mm 7.0x85mm 7.0x90mm 7.0x95mm 8.0x35mm 8.0x40mm 8.0x45mm 8.0x50mm 8.0x55mm 8.0x60mm 8.0x65mm 8.0x70mm 8.0x80mm 8.0x90mm 8.0x100mm	SSS6035, SSS6040, SSS6045, SSS6050, SSS6055, SSS7040, SSS7045, SSS7050, SSS7055, SSS7060, SSS7070, SSS7080, SSS7090, SSS7100, SSS8035, SSS8040, SSS8045, SSS8050, SSS8055, SSS8060, SSS8070, SSS8080, SSS8090, SSS80100	61325
SUPERMED FLEX RIGID	5.5x40, 5.5x50, 5.5x60, 5.5x70, 5.5x80, 5.5x90, 5.5x100, 5.5x110, 5.5x120, 5.5x130, 5.5x140, 5.5x150, 5.5x160, 5.5x170, 5.5x180, 5.5x190, 5.5x200, 5.5x210, 5.5x220, 5.5x230, 5.5x240, 5.5x250, 5.5x260, 5.5x270, 5.5x280, 5.5x290, 5.5x300, 5.5x310, 5.5x320, 5.5x330, 5.5x340, 5.5x350, 5.5x360, 5.5x370, 5.5x380, 5.5x390, 5.5x400, 5.5x410, 5.5x420, 5.5x430, 5.5x440, 5.5x450, 5.5x460, 5.5x470, 5.5x480, 5.5x490, 5.5x500, 5.5x510, 5.5x520, 5.5x530, 5.5x540, 5.5x550, 5.5x560, 5.5x570, 5.5x580, 5.5x590, 5.5x600, 5.5x610, 5.5x620, 5.5x630, 5.5x640, 5.5x650, 5.5x660, 5.5x670, 5.5x680, 5.5x690, 5.5x700, 5.5x710, 5.5x720, 5.5x730, 5.5x740, 5.5x750, 5.5x760, 5.5x770, 5.5x780, 5.5x790, 5.5x800, 5.5x810, 5.5x820, 5.5x830, 5.5x840, 5.5x850, 5.5x860, 5.5x870, 5.5x880, 5.5x890, 5.5x900, 5.5x910, 5.5x920, 5.5x930, 5.5x940, 5.5x950, 5.5x960, 5.5x970, 5.5x980, 5.5x990, 5.5x1000, 5.5x1010, 5.5x1020, 5.5x1030, 5.5x1040, 5.5x1050, 5.5x1060, 5.5x1070, 5.5x1080, 5.5x1090, 5.5x1100, 5.5x1110, 5.5x1120, 5.5x1130, 5.5x1140, 5.5x1150, 5.5x1160, 5.5x1170, 5.5x1180, 5.5x1190, 5.5x1200, 5.5x1210, 5.5x1220, 5.5x1230, 5.5x1240, 5.5x1250, 5.5x1260, 5.5x1270, 5.5x1280, 5.5x1290, 5.5x1300, 5.5x1310, 5.5x1320, 5.5x1330, 5.5x1340, 5.5x1350, 5.5x1360, 5.5x1370, 5.5x1380, 5.5x1390, 5.5x1400, 5.5x1410, 5.5x1420, 5.5x1430, 5.5x1440, 5.5x1450, 5.5x1460, 5.5x1470, 5.5x1480, 5.5x1490, 5.5x1500, 5.5x1510, 5.5x1520, 5.5x1530, 5.5x1540, 5.5x1550, 5.5x1560, 5.5x1570, 5.5x1580, 5.5x1590, 5.5x1600, 5.5x1610, 5.5x1620, 5.5x1630, 5.5x1640, 5.5x1650, 5.5x1660, 5.5x1670, 5.5x1680, 5.5x1690, 5.5x1700, 5.5x1710, 5.5x1720, 5.5x1730, 5.5x1740, 5.5x1750, 5.5x1760, 5.5x1770, 5.5x1780, 5.5x1790, 5.5x1800, 5.5x1810, 5.5x1820, 5.5x1830, 5.5x1840, 5.5x1850, 5.5x1860, 5.5x1870, 5.5x1880, 5.5x1890, 5.5x1900, 5.5x1910, 5.5x1920, 5.5x1930, 5.5x1940, 5.5x1950, 5.5x1960, 5.5x1970, 5.5x1980, 5.5x1990, 5.5x2000, 5.5x2010, 5.5x2020, 5.5x2030, 5.5x2040, 5.5x2050, 5.5x2060, 5.5x2070, 5.5x2080, 5.5x2090, 5.5x2100, 5.5x2110, 5.5x2120, 5.5x2130, 5.5x2140, 5.5x2150, 5.5x2160, 5.5x2170, 5.5x2180, 5.5x2190, 5.5x2200, 5.5x2210, 5.5x2220, 5.5x2230, 5.5x2240, 5.5x2250, 5.5x2260, 5.5x2270, 5.5x2280, 5.5x2290, 5.5x2300, 5.5x2310, 5.5x2320, 5.5x2330, 5.5x2340, 5.5x2350, 5.5x2360, 5.5x2370, 5.5x2380, 5.5x2390, 5.5x2400, 5.5x2410, 5.5x2420, 5.5x2430, 5.5x2440, 5.5x2450, 5.5x2460, 5.5x2470, 5.5x2480, 5.5x2490, 5.5x2500, 5.5x2510, 5.5x2520, 5.5x2530, 5.5x2540, 5.5x2550, 5.5x2560, 5.5x2570, 5.5x2580, 5.5x2590, 5.5x2600, 5.5x2610, 5.5x2620, 5.5x2630, 5.5x2640, 5.5x2650, 5.5x2660, 5.5x2670, 5.5x2680, 5.5x2690, 5.5x2700, 5.5x2710, 5.5x2720, 5.5x2730, 5.5x2740, 5.5x2750, 5.5x2760, 5.5x2770, 5.5x2780, 5.5x2790, 5.5x2800, 5.5x2810, 5.5x2820, 5.5x2830, 5.5x2840, 5.5x2850, 5.5x2860, 5.5x2870, 5.5x2880, 5.5x2890, 5.5x2900, 5.5x2910, 5.5x2920, 5.5x2930, 5.5x2940, 5.5x2950, 5.5x2960, 5.5x2970, 5.5x2980, 5.5x2990, 5.5x3000, 5.5x3010, 5.5x3020, 5.5x3030, 5.5x3040, 5.5x3050, 5.5x3060, 5.5x3070, 5.5x3080, 5.5x3090, 5.5x3100, 5.5x3110, 5.5x3120, 5.5x3130, 5.5x3140, 5.5x3150, 5.5x3160, 5.5x3170, 5.5x3180, 5.5x3190, 5.5x3200, 5.5x3210, 5.5x3220, 5.5x3230, 5.5x3240, 5.5x3250, 5.5x3260, 5.5x3270, 5.5x3280, 5.5x3290, 5.5x3300, 5.5x3310, 5.5x3320, 5.5x3330, 5.5x3340, 5.5x3350, 5.5x3360, 5.5x3370, 5.5x3380, 5.5x3390, 5.5x3400, 5.5x3410, 5.5x3420, 5.5x3430, 5.5x3440, 5.5x3450, 5.5x3460, 5.5x3470, 5.5x3480, 5.5x3490, 5.5x3500, 5.5x3510, 5.5x3520, 5.5x3530, 5.5x3540, 5.5x3550, 5.5x3560, 5.5x3570, 5.5x3580, 5.5x3590, 5.5x3600, 5.5x3610, 5.5x3620, 5.5x3630, 5.5x3640, 5.5x3650, 5.5x3660, 5.5x3670, 5.5x3680, 5.5x3690, 5.5x3700, 5.5x3710, 5.5x3720, 5.5x3730, 5.5x3740, 5.5x3750, 5.5x3760, 5.5x3770, 5.5x3780, 5.5x3790, 5.5x3800, 5.5x3810, 5.5x3820, 5.5x3830, 5.5x3840, 5.5x3850, 5.5x3860, 5.5x3870, 5.5x3880, 5.5x3890, 5.5x3900, 5.5x3910, 5.5x3920, 5.5x3930, 5.5x3940, 5.5x3950, 5.5x3960, 5.5x3970, 5.5x3980, 5.5x3990, 5.5x4000, 5.5x4010, 5.5x4020, 5.5x4030, 5.5x4040, 5.5x4050, 5.5x4060, 5.5x4070, 5.5x4080, 5.5x4090, 5.5x4100, 5.5x4110, 5.5x4120, 5.5x4130, 5.5x4140, 5.5x4150, 5.5x4160, 5.5x4170, 5.5x4180, 5.5x4190, 5.5x4200, 5.5x4210, 5.5x4220, 5.5x4230, 5.5x4240, 5.5x4250, 5.5x4260, 5.5x4270, 5.5x4280, 5.5x4290, 5.5x4300, 5.5x4310, 5.5x4320, 5.5x4330, 5.5x4340, 5.5x4350, 5.5x4360, 5.5x4370, 5.5x4380, 5.5x4390, 5.5x4400, 5.5x4410, 5.5x4420, 5.5x4430, 5.5x4440, 5.5x4450, 5.5x4460, 5.5x4470, 5.5x4480, 5.5x4490, 5.5x4500, 5.5x4510, 5.5x4520, 5.5x4530, 5.5x4540, 5.5x4550, 5.5x4560, 5.5x4570, 5.5x4580, 5.5x4590, 5.5x4600, 5.5x4610, 5.5x4620, 5.5x4630, 5.5x4640, 5.5x4650, 5.5x4660, 5.5x4670, 5.5x4680, 5.5x4690, 5.5x4700, 5.5x4710, 5.5x4720, 5.5x4730, 5.5x4740, 5.5x4750, 5.5x4760, 5.5x4770, 5.5x4780, 5.5x4790, 5.5x4800, 5.5x4810, 5.5x4820, 5.5x4830, 5.5x4840, 5.5x4850, 5.5x4860, 5.5x4870, 5.5x4880, 5.5x4890, 5.5x4900, 5.5x4910, 5.5x4920, 5.5x4930, 5.5x4940, 5.5x4950, 5.5x4960, 5.5x4970, 5.5x4980, 5.5x4990, 5.5x5000, 5.5x5010, 5.5x5020, 5.5x5030, 5.5x5040, 5.5x5050, 5.5x5060, 5.5x5070, 5.5x5080, 5.5x5090, 5.5x5100, 5.5x5110, 5.5x5120, 5.5x5130, 5.5x5140, 5.5x5150, 5.5x5160, 5.5x5170, 5.5x5180, 5.5x5190, 5.5x5200, 5.5x5210, 5.5x5220, 5.5x5230, 5.5x5240, 5.5x5250, 5.5x5260, 5.5x5270, 5.5x5280, 5.5x5290, 5.5x5300, 5.5x5310, 5.5x5320, 5.5x5330, 5.5x5340, 5.5x5350, 5.5x5360, 5.5x5370, 5.5x5380, 5.5x5390, 5.5x5400, 5.5x5410, 5.5x5420, 5.5x5430, 5.5x5440, 5.5x5450, 5.5x5460, 5.5x5470, 5.5x5480, 5.5x5490, 5.5x5500, 5.5x5510, 5.5x5520, 5.5x5530, 5.5x5540, 5.5x5550, 5.5x5560, 5.5x5570, 5.5x5580, 5.5x5590, 5.5x5600, 5.5x5610, 5.5x5620, 5.5x5630, 5.5x5640, 5.5x5650, 5.5x5660, 5.5x5670, 5.5x5680, 5.5x5690, 5.5x5700, 5.5x5710, 5.5x5720, 5.5x5730, 5.5x5740, 5.5x5750, 5.5x5760, 5.5x5770, 5.5x5780, 5.5x5790, 5.5x5800, 5.5x5810, 5.5x5820, 5.5x5830, 5.5x5840, 5.5x5850, 5.5x5860, 5.5x5870, 5.5x5880, 5.5x5890, 5.5x5900, 5.5x5910, 5.5x5920, 5.5x5930, 5.5x5940, 5.5x5950, 5.5x5960, 5.5x5970, 5.5x5980, 5.5x5990, 5.5x6000, 5.5x6010, 5.5x6020, 5.5x6030, 5.5x6040, 5.5x6050, 5.5x6060, 5.5x6070, 5.5x6080, 5.5x6090, 5.5x6100, 5.5x6110, 5.5x6120, 5.5x6130, 5.5x6140, 5.5x6150, 5.5x6160, 5.5x6170, 5.5x6180, 5.5x6190, 5.5x6200, 5.5x6210, 5.5x6220, 5.5x6230, 5.5x6240, 5.5x6250, 5.5x6260, 5.5x6270, 5.5x6280, 5.5x6290, 5.5x6300, 5.5x6310, 5.5x6320, 5.5x6330, 5.5x6340, 5.5x6350, 5.5x6360, 5.5x6370, 5.5x6380, 5.5x6390, 5.5x6400, 5.5x6410, 5.5x6420, 5.5x6430, 5.5x6440		



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SUPERMED MONOAXIAL REDUCTION RESCUE SCREW	3.5x25 MM, 3.5x30 MM, 3.5x35 MM, 3.5x40 MM, 3.5x45 MM, 4.0x25 MM, 4.0x30 MM, 4.0x35 MM, 4.0x40 MM, 4.0x45 MM, 4.5x20 MM, 4.5x25 MM, 4.5x30 MM, 4.5x35 MM, 4.5x40 MM, 4.5x45 MM, 5.0x25 MM, 5.0x30 MM, 5.0x40 MM, 5.0x45 MM, 5.0x50 MM, 5.5x20 MM, 5.5x25 MM, 5.5x30 MM, 5.5x35 MM, 5.5x40 MM, 5.5x45 MM, 5.5x50 MM, 5.5x55 MM, 6.0x25 MM, 6.0x30 MM, 6.0x35 MM, 6.0x40 MM, 6.0x45 MM, 6.0x50 MM, 6.0x55 MM, 6.0x60 MM, 6.2x25 MM, 6.2x30 MM, 6.2x35 MM, 6.2x40 MM, 6.2x45 MM, 6.2x50 MM, 6.2x55 MM, 6.2x60 MM, 6.5x25 MM, 6.5x30 MM, 6.5x35 MM, 6.5x40 MM, 6.5x45 MM, 6.5x50 MM, 6.5x55 MM, 6.5x60 MM, 7.0x25 MM, 7.0x30 MM, 7.0x35 MM, 7.0x40 MM, 7.0x45 MM, 7.0x50 MM, 7.0x55 MM, 7.0x60 MM, 7.5x25 MM, 7.5x30 MM, 7.5x35 MM, 7.5x40 MM, 7.5x45 MM, 7.5x50 MM, 7.5x55 MM, 7.5x60 MM, 8.0x30 MM, 8.0x35 MM, 8.0x40 MM, 8.0x45 MM, 8.0x50 MM, 8.0x55 MM, 8.0x60 MM, 8.0x65 MM, 8.0x70 MM, 8.0x80 MM, 8.0x90 MM, 8.0x100 MM	PASTLK3525, PASTLK3530, PASTLK3535, PASTLK3540, PASTLK3545, PASTLK4025, PASTLK4030, PASTLK4035, PASTLK4040, PASTLK4045, PASTLK4520, PASTLK4525, PASTLK4530, PASTLK4535, PASTLK4540, PASTLK4545, PASTLK5025, PASTLK5030, PASTLK5035, PASTLK5040, PASTLK5045, PASTLK5050, PASTLK5520, PASTLK5525, PASTLK5530, PASTLK5535, PASTLK5540, PASTLK5545, PASTLK5550, PASTLK5555, PASTLK6025, PASTLK6030, PASTLK6035, PASTLK6040, PASTLK6045, PASTLK6050, PASTLK6055, PASTLK6060, PASTLK6225, PASTLK6230, PASTLK6235, PASTLK6240, PASTLK6245, PASTLK6250, PASTLK6255, PASTLK6525, PASTLK6530, PASTLK6535, PASTLK6540, PASTLK6545, PASTLK6550, PASTLK6555, PASTLK6560, PASTLK7025, PASTLK7030, PASTLK7035, PASTLK7040, PASTLK7045, PASTLK7050, PASTLK7055, PASTLK7060, PASTLK7525, PASTLK7530, PASTLK7535, PASTLK7540, PASTLK7545, PASTLK7550, PASTLK7555, PASTLK7560, PASTLK8030, PASTLK8035, PASTLK8040, PASTLK8045, PASTLK8050, PASTLK8055, PASTLK8060, PASTLK8065, PASTLK8070, PASTLK8080, PASTLK8090, PASTLK80100	61325
SUPERMED POLYAXIAL CANNULATED RESCUE SCREW	3.5x25 MM, 3.5x30 MM, 3.5x35 MM, 3.5x40 MM, 3.5x45 MM, 4.0x25 MM, 4.0x30 MM, 4.0x35 MM, 4.0x40 MM, 4.0x45 MM, 4.5x20 MM, 4.5x25 MM, 4.5x30 MM, 4.5x35 MM, 4.5x40 MM, 4.5x45 MM, 5.0x25 MM, 5.0x30 MM, 5.0x40 MM, 5.0x45 MM, 5.0x50 MM, 5.5x20 MM, 5.5x25 MM, 5.5x30 MM, 5.5x35 MM, 5.5x40 MM, 5.5x45 MM, 5.5x50 MM, 5.5x55 MM, 6.0x25 MM, 6.0x30 MM, 6.0x35 MM, 6.0x40 MM, 6.0x45 MM, 6.0x50 MM, 6.0x55 MM, 6.0x60 MM, 6.2x25 MM, 6.2x30 MM, 6.2x35 MM, 6.2x40 MM, 6.2x45 MM, 6.2x50 MM, 6.2x55 MM, 6.2x60 MM, 6.5x25 MM, 6.5x30 MM, 6.5x35 MM, 6.5x40 MM, 6.5x45 MM, 6.5x50 MM, 6.5x55 MM, 6.5x60 MM, 7.0x25 MM, 7.0x30 MM, 7.0x35 MM, 7.0x40 MM, 7.0x45 MM, 7.0x50 MM, 7.0x55 MM, 7.0x60 MM, 7.5x25 MM, 7.5x30 MM, 7.5x35 MM, 7.5x40 MM, 7.5x45 MM, 7.5x50 MM, 7.5x55 MM, 7.5x60 MM, 8.0x30 MM, 8.0x35 MM, 8.0x40 MM, 8.0x45 MM, 8.0x50 MM, 8.0x55 MM, 8.0x60 MM, 8.0x65 MM, 8.0x70 MM, 8.0x80 MM, 8.0x90 MM, 8.0x100 MM	PASC3525, PASC3530, PASC3535, PASC3540, PASC3545, PASC4025, PASC4030, PASC4035, PASC4040, PASC4045, PASC4520, PASC4525, PASC4530, PASC4535, PASC4540, PASC4545, PASC5025, PASC5030, PASC5035, PASC5040, PASC5045, PASC5520, PASC5525, PASC5530, PASC5535, PASC5540, PASC5545, PASC5550, PASC6025, PASC6030, PASC6035, PASC6040, PASC6045, PASC6050, PASC6055, PASC6060, PASC6225, PASC6230, PASC6235, PASC6240, PASC6245, PASC6250, PASC6255, PASC6525, PASC6530, PASC6535, PASC6540, PASC6545, PASC6550, PASC6555, PASC6560, PASC7025, PASC7030, PASC7035, PASC7040, PASC7045, PASC7050, PASC7055, PASC7060, PASC7525, PASC7530, PASC7535, PASC7540, PASC7545, PASC7550, PASC7555, PASC7560, PASC8030, PASC8035, PASC8040, PASC8045, PASC8050, PASC8055, PASC8060, PASC8065, PASC8070, PASC8080, PASC8090, PASC80100	61325
SUPERMED MONOAXIAL CANNULATED RESCUE SCREW	3.5x25 MM, 3.5x30 MM, 3.5x35 MM, 3.5x40 MM, 3.5x45 MM, 4.0x25 MM, 4.0x30 MM, 4.0x35 MM, 4.0x40 MM, 4.0x45 MM, 4.5x20 MM, 4.5x25 MM, 4.5x30 MM, 4.5x35 MM, 4.5x40 MM, 4.5x45 MM, 5.0x25 MM, 5.0x30 MM, 5.0x40 MM, 5.0x45 MM, 5.0x50 MM, 5.5x20 MM, 5.5x25 MM, 5.5x30 MM, 5.5x35 MM, 5.5x40 MM, 5.5x45 MM, 5.5x50 MM, 5.5x55 MM, 6.0x25 MM, 6.0x30 MM, 6.0x35 MM, 6.0x40 MM, 6.0x45 MM, 6.0x50 MM, 6.0x55 MM, 6.0x60 MM, 6.2x25 MM, 6.2x30 MM, 6.2x35 MM, 6.2x40 MM, 6.2x45 MM, 6.2x50 MM, 6.2x55 MM, 6.2x60 MM, 6.5x25 MM, 6.5x30 MM, 6.5x35 MM, 6.5x40 MM, 6.5x45 MM, 6.5x50 MM, 6.5x55 MM, 6.5x60 MM, 7.0x25 MM, 7.0x30 MM, 7.0x35 MM, 7.0x40 MM, 7.0x45 MM, 7.0x50 MM, 7.0x55 MM, 7.0x60 MM, 7.5x25 MM, 7.5x30 MM, 7.5x35 MM, 7.5x40 MM, 7.5x45 MM, 7.5x50 MM, 7.5x55 MM, 7.5x60 MM, 8.0x30 MM, 8.0x35 MM, 8.0x40 MM, 8.0x45 MM, 8.0x50 MM, 8.0x55 MM, 8.0x60 MM, 8.0x65 MM, 8.0x70 MM, 8.0x80 MM, 8.0x90 MM, 8.0x100 MM	PASMCK3525, PASMCK3530, PASMCK3535, PASMCK3540, PASMCK3545, PASMCK4025, PASMCK4030, PASMCK4035, PASMCK4040, PASMCK4045, PASMCK4520, PASMCK4525, PASMCK4530, PASMCK4535, PASMCK4540, PASMCK4545, PASMCK5025, PASMCK5030, PASMCK5035, PASMCK5040, PASMCK5045, PASMCK5520, PASMCK5525, PASMCK5530, PASMCK5535, PASMCK5540, PASMCK5545, PASMCK5550, PASMCK6025, PASMCK6030, PASMCK6035, PASMCK6040, PASMCK6045, PASMCK6050, PASMCK6055, PASMCK6060, PASMCK6225, PASMCK6230, PASMCK6235, PASMCK6240, PASMCK6245, PASMCK6250, PASMCK6255, PASMCK6525, PASMCK6530, PASMCK6535, PASMCK6540, PASMCK6545, PASMCK6550, PASMCK6555, PASMCK6560, PASMCK7025, PASMCK7030, PASMCK7035, PASMCK7040, PASMCK7045, PASMCK7050, PASMCK7055, PASMCK7060, PASMCK7525, PASMCK7530, PASMCK7535, PASMCK7540, PASMCK7545, PASMCK7550, PASMCK7555, PASMCK7560, PASMCK8030, PASMCK8035, PASMCK8040, PASMCK8045, PASMCK8050, PASMCK8055, PASMCK8060, PASMCK8065, PASMCK8070, PASMCK8080, PASMCK8090, PASMCK80100	61325
SUPERMED LORDOTIC MODULER PLATE TITANIUM	5*435MM, 5*455MM, 8*20MM, 8*25MM, 8*30MM, 8*40MM, 8*45MM, 8*50MM, 8*60MM,	LMP5535, LMP5545, LMP820, LMP825, LMP830, LMP835, LMP840, LMP845, LMP850, LMP860	61325
SUPERMED HOOK	3,0MM, 3,5MM, 5,0MM, 5,5MM, 7,0MM, 7,5MM, 8,0MM, 8,5MM	LMPH30, LMPH35, LMPH50, LMPH55, LMPH70, LMPH75, LMPH80, LMPH85	61325
SUPERMED INTERFACE CONNECTOR	3,0MM, 3,5MM, 5,0MM, 5,5MM, 7,0MM, 7,5MM, 8,0MM, 8,5MM	LMPA30, LMPA35, LMPA50, LMPA55, LMPA70, LMPA75, LMPA80, LMPA85	61325
SUPERMED TOROCOLUMBAR GROOVED Ti ROD	8x50, 8x75, 8x100, 8x125, 8x150, 8x175, 8x200, 9x50, 9x75, 9x100, 9x125, 9x150, 9x175, 9x200, 10x50, 10x75, 10x100, 10x125, 10x150, 10x175, 10x200	SS1YTR850, SS1YTR875, SS1YTR8100, SS1YTR8125, SS1YTR8150, SS1YTR8175, SS1YTR8200, SS1YTR950, SS1YTR975, SS1YTR9100, SS1YTR9125, SS1YTR9150, SS1YTR9175, SS1YTR9200, SS1YTR1050, SS1YTR1075, SS1YTR10100, SS1YTR10125, SS1YTR10150, SS1YTR10175, SS1YTR10200	61325
SUPERMED TOROKOLUMBAR CONNECTOR, Ti, DOMİNO		STKTD	61325
SUPERMED LUMBAR CORPECTOMY CAGE	Ø20[25,34] [32,44] [42,58] [56,84] Ø24[23,29] [28,40] [38,54] [52,76] [74,114] Ø28 [30,44] [42,58] [56,84] [82,130] [100,140]	LCC202534, LCC203244, LCC204258, LCC205684 LCC242329, LCC242840, LCC243854, LCC245276, LCC2474114 LCC283044, LCC284258, LCC285684, LCC2882130, LCC28100140	38161
SUPERMED LUMBAR CORPECTOMY CAGE ANGLED	Ø20mm[25,34] [32,44] [42,58] [56,84] Ø24mm[23,29] [28,40] [38,54] [52,76] [74,114] Ø28mm[30,44] [42,58] [56,84] [82,130] [100,140]	LCC202534, LCC203244, LCC204258, LCC205684 LCC242329, LCC242840, LCC243854, LCC245276, LCC2474114 LCC283044, LCC284258, LCC285684, LCC2882130, LCC28100140	38161
SUPERMED CERVICAL TITANIUM CORPECTOMY CAGE	Ø10mm[10,13] [10,17] [16,25] Ø12mm[10,13] [10,17] [16,25] [24,40] [39,65] Ø14mm[10,13] [10,17] [16,25] [24,40] [39,65] Ø16mm[10,13] [10,17] [16,25] [24,40] [39,65] Ø20mm[10,13] [10,17] [16,25]	CC101013, CC101017, CC101625 CC121013, CC121017, CC121625, CC122440, CC123965 CC141013, CC141017, CC141625, CC142440, CC143965 CC161013, CC161017, CC161625, CC162440, CC163965 CC201013, CC201017, CC201625	38161
SUPERMED CERVICAL TITANIUM CORPECTOMY CAGE 6 ANGLED	Ø12mm[16,25] [24,40] [39,65] Ø14mm[16,25] [24,40] [39,65]	CCA121625, CCA122440, CCA123965 CCA141625, CCA142440, CCA143965	38161
SUPERMED CORPECTOMY CAGE SCREW		CCS	38161
SUPERMED TYPE II COATED CERVICAL POSTERIOR SCREW	3.5x10mm, 3.5x12mm, 3.5x14mm, 3.5x16mm, 3.5x18mm, 3.5x20mm, 3.5x22mm, 3.5x24mm, 3.5x26mm, 3.5x28mm, 3.5x30mm, 3.5x32mm, 3.5x34mm, 3.5x36mm, 3.5x38mm, 3.5x40mm, 4.0x10mm, 4.0x12mm, 4.0x14mm, 4.0x16mm, 4.0x18mm, 4.0x20mm, 4.0x22mm, 4.0x24mm, 4.0x26mm, 4.0x28mm, 4.0x30mm, 4.0x32mm, 4.0x34mm, 4.0x36mm, 4.0x38mm, 4.0x40mm, 4.0x42mm, 4.0x44mm, 4.0x46mm	SPPS3510, SPPS3512, SPPS3514, SPPS3516, SPPS3518, SPPS3520, SPPS3522, SPPS3524, SPPS3526, SPPS3528, SPPS3530, SPPS3532, SPPS3534, SPPS3536, SPPS3538, SPPS3540, SPPS4010, SPPS4012, SPPS4014, SPPS4016, SPPS4018, SPPS4020, SPPS4022, SPPS4024, SPPS4026, SPPS4028, SPPS4030, SPPS4032, SPPS4034, SPPS4036, SPPS4038, SPPS4040, SPPS4042, SPPS4044, SPPS4046	61325
SUPERMED SPINAL STABILIZATION STICK DIA	3.5x40mm, 3.5x80mm, 3.5x120mm, 3.5x200mm	SPSS1304, SPSS1308, SPSS1312, SPSS1320	61325
SUPERMED OCCIPITAL PLATE	SHORT, LONG	SOCPS, SOCP	61325



Certificate of Registration

This is to certify that

**Quality Management System
for Medical Devices**

of

TOLMED MEDİKAL TEKSTİL SAN. VE TİC.LTD.ŞTİ.

HUZUR MAH. 1218. CAD. NO: 5/B
ÇANKAYA - ANKARA / TÜRKİYE

complies with requirements of

ISO 13485:2016

This certificate is valid concerning all activities related to;

PRODUCTION AND SALES OF SPINAL IMPLANTS

OMURGA İMPLANTLARI ÜRETİMİ VE SATIŞI

ISO 02 745 811
Certificate No.

Oct. 1, 2020
Date of this Certificate

Oct. 7, 2021
Certification Expiry Date

Sep. 23, 2020
Date of Audit

Oct. 8, 2019
Date of Registration


Managing Director / Director



Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
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This certificate is only valid if it is available/valid on Medicert website at www.medicert.com.tr



This certificate of Registration remains the property of Medicert Certificate Ltd and shall be returned immediately upon request
* In Case if Surveillance Audit is not allowed to be conducted on or before the specified date; the Certificate shall be Suspended/Withdrawn.

NO	PRODUCT NAME	CATALOG REF	PICTURES	Material
1	SUPERMED POLYAXIAL SCREW WITH ROD DIA 5,5mm	PAS		Ti6Ai4V
2	SUPERMED POLYAXIAL SCREW WITH ROD DIA 6mm Poz.nr 3	SPA		Ti6Ai4V
3	SUPERMED CANNULATED POLYAXIAL SCREW (CEMENT TYPE)	SMC		Ti6Ai4V
4	SUPERMED MONOAXIAL SCREW Poz.nr 2	MAS		Ti6Ai4V
5	SUPERMED REDUCTION MONOAXIAL SCREW Poz.nr 4	SMRS		Ti6Ai4V
6	SUPERMED REDUCTION POLYAXIAL SCREW Poz.nr 5	SPRS		Ti6Ai4V
7	SUPERMED ROD 40mm-120mm	SR		Ti6Ai4V
8	SUPERMED ROD 130mm-300mm Poz.nr 1	SR		Ti6Ai4V
9	SUPERMED ROD 400mm-600mm	SR		Ti6Ai4V
10	SUPERMED MULTIAXIAL TRANSVERSE CONNECTOR SUPERMED CROSS CONNECTOR SUPERMED TRANSVERSE LINK Poz. nr 6	TL TLR MTL		Ti6Ai4V

1	STERILE SUPERMED CERVICAL PEEK CAGE	SYA		PEEK
2	STERILE SUPERMED CERVICAL BLADED PEEK CAGE	SSCPSB		PEEK
3	STERILE SUPERMED EXPANDABLE CERVICAL PEEK CAGE	SECPC		PEEK
4	STERILE SUPERMED LUMBAR FUSION PEEK CAGE	SLCD		PEEK
5	STERILE SUPERMED TLIF PEEK CAGE	SBC		PEEK
6	STERILE SUPERMED EXPANDABLE LUMBAR PEEK CAGE	SYAL		PEEK
7	SUPERMED LUMBAR CORPECTOMY CAGE	LCC		Ti6Al4V
8	SUPERMED CERVICAL CORPECTOMY CAGE	CC		Ti6Al4V
9	STERILE SUPERMED CERVICAL DISC PROTHESIS	SSCD		Ti6Al4V
1	SUPERMED CERVICAL ANTERIOR PLATE	CAP		Ti6Al4V
2	SUPERMED ANTERIOR PLATE SCREW	CAPS		Ti6Al4V

1	SUPERMED OCCIPITAL PLATE	SOCPS		Ti6Ai4V
2	SUPERMED OCCIPITAL PLATE SCREW	CCS		Ti6Ai4V
3	SUPERMED POSTERIOR POLYAXIAL SCREW	SPPPS		Ti6Ai4V
4	SUPERMED POSTERIOR ROD DIA	SPSS		Ti6Ai4V
1	SUPERMED DOMINO CONNECTOR	SSTKTD		Ti6Ai4V
2	SUPERMED LATERAL CONNECTOR	LCNT		Ti6Ai4V
3	SUPERMED PEDICULAR HOOK Poz nr.7	PH PHF		Ti6Ai4V
4	SUPERMED LAMINAR HOOK Poz.nr 7	LHA LHR LHF		Ti6Ai4V