



EEC CERTIFICATE

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II

Company Name : Norm Tıbbi Ürünler İth. İhr. San. ve Tic. Ltd. Şti.

Company Address : Nasuh Akar Mah. 1403. Sok. No:3 Balgat Çankaya ANKARA / TÜRKİYE

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex II
(Excluding Section 4)

Product : Non Sterile Spinal Screw System - Class IIb
Non Sterile Thoracolumbar Plate System - Class IIb
Sterile Lumbar and Cervical Peek Cage - Class IIb
Sterile Lumbar and Cervical Corpectomy Cage - Class IIb
Sterile Cervical Plate - Class IIb
Sterile and Non Sterile Cervical Disc Prosthesis - Class IIb

GMDN : 61325, 60847, 61324, 48164, 61865, 38161

Product Types are attached.

Certificate Number : M.2012.106.1472
Report Number : UD.1319.YB
Initial Assessment Date : 30.08.2012
Registration Date : 12.09.2012
Recertification Assessment Date : 23.08.2017
Reissue Date / No : 13.11.2017/01
Revision Date /No : 03.04.2018/01
Expiry Date : 11.09.2022

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

The certificate is not in force between 11.09.2017-13.11.2017.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC 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. 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 currency of the certificate can be checked through www.udem.com.tr.

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This document containing 3 (three) pages is the Annex of the Certificate with the revision number 01, with the number M.2012.106.1472 and with the registration date of 12.09.2012 and with the revision date of 03.04.2018 issued for "Norm Tıbbi Ürünler İth. İhr. 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

NORM POLYAXIAL SCREW+SET SCREW	NSPA (35...80)(25...100)
NORM TITANIUM POLYAXIAL SCREW+SET SCREW	NPCSS(35...45)(08...42)
NORM POSTERIOR CERVICAL POLYAXIAL SCREW+SET SCREW	NPCSS(35...45)(08...42)
NORM CANNULATED POLYAXIAL SCREW+SET SCREW	NCPS (35...80)(25...100)
NORM POLYAXIAL HOLES SCREW+SET SCREW	NSPAH(35...80)(25...100)
NORM MONOAXIAL SCREW+SET SCREW	NSMA(35...80)(25...100)
NORM POLYAXIAL SCREW SELF TAPPING+SET SCREW	NSPAK (35...80)(20...100)
NORM REDUCTION-POLYAXIAL SCREW+SET SCREW	NSPRS(35...80)(25...100)
NORM MONOAXIAL LITHESIS SCREW (LONG TYPE)+SET SCREW	NSMRS(35...80)(25...100)
NORM ANTERIOR ROD	NSAR16(04...25)
NORM TRANSVERSE CONNECTOR (LINK)	NSTL (140...180)
NORM TRANSVERSE CONNECTOR ROD	NSTLR (140...180)
NORM TRANSVERSE CONNECTOR HOOK	NSTLH
NORM TRANSVERSE CONNECTOR MULTIAXIAL	NSATL (20...80)(20...100)
NORM LATERAL CONNECTOR	NSLCNT (15...20)
NORM LATERAL-DOMINO CONNECTOR FOR ROD	NNSECNT(01,02)
NORM OMNIAxIAL CONNECTOR	NNSOCNT
NORM PEDICULAR HOOK FLEXIBLE	NPHF05(05...07)
NORM LAMINAR HOOK SMALL NARROW WITH BLADE	NPLH(05...07)(05...11)
NORM LAMINAR RIGHT ANGLED HOOK SMALL NARROW WITH BLADE	NPLHLA7(9...11)
NORM LAMINAR LEFT ANGLED HOOK SMALL NARROW WITH BLADE	NPLHRA7(09...11)
NORM LAMINAR HOOK FLEXIBLE	NLHF05(05...07)
NORM HOOK TYPE3 LEFT	NHT3L05(7...11)
NORM HOOK TYPE3 RIGHT	NHT3R05(7...11)
NORM DYNAMIC ROD	NDNR6(050...500)
NORM DYNAMIC SCREW	NDNS(55...75)(30...60)
NORM SACRAL CONNECTOR	NSSC(15...20)
NORM SACRAL SCREW	NSSS(60...70)(30...60)
NORM SACRAL ILLIAC SCREW	NSIS(70...90)(30...100)
NORM PEDICULAR HOOK SMALL	NPPH(05...08)(05...09)
NORM HEMISPHERICAL MULTIAXIAL SCREW	MYSPN(50...80)-(30...60)P
NORM HEMISPHERICAL MONOAXIAL SCREW	MYSPN(50...80)-(30...60)M
NORM MODULER RIGID PLATE	MYSPN(2...5)MRP(S,L,SC)
NORM MODULER DYNAMIC PLATE	MYSPN(2,3)MDP(S,L)
NORM MODULER DOUBLE DYNAMIC PLATE	MYSPN3MDP(S,L)D
NORM MODULER SEMI-RIGID PLATE	MYSPN(2...5)NSRP(S,L)
NORM HEMISPHERICAL NUT	NMYSPNN(50...80)
NORM TITANIUM ROD	MYSPN55-(045...170)R
NORM TRANSVERSE CONNECTOR(LINK)	MYSPN(50...80)TB
NORM TRANSVERSE LINK CONNECTOR	MYSPNLC(50...80)TB
NORM MYSPINE TRANSVERSE CONNECTOR MULTIAXIAL	MYSPN-TBA(20...80)(40...120)
NORM CONNECTOR CLAMP	NMYSPN-(CC,ICC,MCC)
NORM ROD	NSR155(04...600)
NORM ROD	NSR16(04...600)
NORM PEDIS PEDIATRIC POLYAXIAL SCREW+SET SCREW	PPAS(35...50)(20...50)
NORM PEDIS PEDIATRIC SPONDILOLITHESIS POLYAXIAL SCREW+SET SCREW	SPPAS(40...50)(35...50)
NORM PEDIS PEDIATRIC ROD	PPR(40...500)
NORM PEDIS PEDIATRIC TRANSVERSE CONNECTOR	PTC(40...60)
NORM PEDIS PEDIATRIC ROD CONNECTOR	PPRC(50...75)(50...60)
NORM PEDIS PEDIATRIC LATERAL CONNECTOR	PPLC
NORM PEDIS PEDIATRIC AXIAL CONNECTOR	PPAC
NORM PEDIS PEDIATRIC LAMINAR HOOK	PLH(40...50)(55...75)
NORM PEDIS PEDIATRIC PEDICULAR HOOK	PPH75(55...65)
NORM TITANIUM CANCELLOUS BONE SCREW	NPCCB(35...45)(06...20)
NORM TITANIUM OCCIPITAL PLATE	NPCHF(S,M,L)
NORM POSTERIOR CERVICAL OCCIPITAL PLATE WITH ROD	NPCRW(S,L)
NORM TITANIUM OCCIPITOCERVICAL ROD 45 ANGLED	NPCORA
NORM POLYAXIAL ROD LEFT-RIGHT	NPCPRD
NORM ROD CONNECTOR	NPCRC35(35...60)
NORM TITANIUM CORTICAL BONE SCREW+SET SCREW	NPCSCB40(26...40)
NORM TITANIUM POSTERIOR CERVICAL PLATE SCREW	NPCTOS(35...40)(06...20)
NORM TITANIUM PLATE	NPCSP(15...65)
NORM 18 DEGREE ANGLED HOOK	NPCLHA18
NORM LATERAL CONNECTOR	NPCLC(10...12)
NORM TITANIUM ROD	NPCTR(12...24)
NORM POSTERIOR CERVICAL INSIDE-OUTSIDE SCREW+SET SCREW	NPCIOS
NORM POSTERIOR CERVICAL TRANSVERSE CONNECTOR	NPCTL(40...80)
NORM KYPHOTIC MODULER PLATE	KYP(S,M,L)

SPINAL SCREW SYSTEM - GMDN Code:
Steril: 61324 Nonsteril: 61325



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NORM LORDOTIC MODULER PLATE	LRD(S,M,L)	
NORM LATERAL MEDIAL MODULER PLATE (5 NODE, 7 NODE)	LM(01,02)	
NORM LAMINAR HOOK	NPCLH(04)(5...7)(45...65)	
NORM SACRUM MODULER PLATE	SAC(S,L)	
NORM MONOAXIAL SCREW SELF TAPPING+SET SCREW	NSMAK(35...80)(20...100)	
NORM THORACOLUMBAR POSTERIOR POLYAXIAL SCREW, TITANIUM, SACROILLIAC+SET SCREW	NSPRSS(45...80)(20...80)	
NOTA POLYAXIAL SCREW	NOPAS(35...80)(20...80)	
NOTA POLYAXIAL LISTHESIS SCREW	NOPALS(35...80)(20...80)	
NOTA POLYAXIAL SCREW SELF TAPPING	NOPASK(30...80)(20...80)	
NOTA MONOAXIAL SCREW	NOMAS(35...80)(20...80)	
NOTA MONOAXIAL SELF TAPPING	NOMASK(45...65)(25...60)	
NOTA CANNULATED POLYAXIAL SCREW	NOCP(30...80)(20...80)	
NOTA MONOAXIAL LISTHESIS SCREW	NOMALS(35...70)(20...80)	
NOTA THORACOLUMBAR POSTERIOR POLYAXIAL SCREW, TITANIUM, SACROILLIAC	NOPALSS(45...70)(30...60)	
NOTA ROD	NOR16(04...60)	
NOTA TRANSVERSE LINK MULTIAXIAL	NOTML(40...60)(60...80)	
NOTA TRANSVERSE LINK	NOTRL(100...200)	
NOTA DOMINO CONNECTOR 1,2 ROD	NOECNT(01,02)	
NOTA LATERAL CONNECTOR	NOLCNT(15...20)	
NOTA LAMINAR HOOK SMALL NARROW WITH BLADE	NOLHO(5...7)(5...11)	
NOTA LAMINAR LEFT VE RIGHT ANGLED ANGLED 20 HOOK SMALL, NARROW WITH BLADE	NOLHRA7(09...11)	
NOTA MULTIAXIAL LAMINAR HOOK SMALL NARROW WITH BLADE	NOMLH(05...07)(05...07)	
NOTA MULTIAXIAL PEDICULAR HOOK SMALL	NOMPH08(05...07)	
NOTA PEDICULAR HOOK SMALL	NOPH08(05...09)	
JOINT WING FASET SCREW	NJW(4...8)813	
JOINT FIX FASET SCREW	NJFFS(45...50)(25...50)	
NORM ROD CONNECTOR	NCPRC(3535)	
NORM CERVICAL DISC PROSTHESIS SCREW	NCDPS(12...20)	
PEDIFIX ROD	PXR(030...480)	
PEDIFIX MONOBLOCK CROSS CONNECTOR	PXMC(12...24)	
PEDIFIX POLYAXIAL CROSS CONNECTOR (SMALL, MEDIUM, LARGE, X-LARGE)	PXPC(24...45)(30...60)	
PEDIFIX MONOAXIAL SCREW	PXMS(40...75)(20...60)	
PEDIFIX POLYAXIAL SCREW	PXPS(40...75)(20...60)	
PEDIFIX PEDICLE HOOK (SMALL, LARGE)	PXPH(S,L)	
PEDIFIX LAMINAR HOOK (SMALL, MEDIUM, LARGE)	PXLH(S,M,L)	
PEDIFIX LAMINAR HOOK ANGLED BLADE	PXLHA	
PEDIFIX THORACIC LAMINAR HOOK RAMPED	PXLHR	
PEDIFIX EXTENDED BODY LAMINAR HOOK	PXLHE	
PEDIFIX TRANSVERSE PROSES HOOK (LEFT,RIGHT)	PXTH(L,R)	
PEDIFIX THORACIC HOOK OFFSET (LEFT,RIGHT)	PXTHO(L,R)	
PEDIFIX SUPRALAMINAR THORACIC HOOK (LEFT,RIGHT)	PXSH(L,R)	
PEDIFIX SINGLE STABLE	PXSS	
PEDIFIX DUAL STAPLE CAUDAL (SMALL, LARGE)	PXDSC(S,L)	
PEDIFIX DUAL STAPLE ROSTRAL (SMALL,LARGE)	PXDSR(S,L)	
PEDIFIX ROD TO ROD CONNECTOR (SMALL, LARGE)	PXPDC(S,L) (45)(45...60)	
PEDIFIX ROD TO ROD CONNECTOR	PXPDC4535	
PEDIFIX OFFSET CONNECTOR	PXOC(30...70)	
PEDIFIX EXTENDED CONNECTOR (SMALL,LARGE)(30...60)	PXEC(S,L)	
PEDIFIX PARALLEL CONNECTOR	PXICO	
PEDIFIX ILIAC CONNECTOR	PXIC(15...45)	
NORM ANTERIOR AGRAFE PLATE (DOUBLE NAIL)	NSAP(L,R)(23...25)	THORACOLUMBAR PLATE SYSTEM - GMDN Code Steril:61324 Nonsteril:61325
NORM ANTERIOR TRANSVERSE ROD CONNECTOR	NSATB(23...25)(15...17)	
NORM NARROW LOCKING PLATE	NNLP(40...120)U	
NORM STRAIGHT LOCKING PLATE	NSLP(70...120)U	
NORM ANTERIOR LUMBAR PLATE LOCKING	NLP(40...120)U	
NORM KYPHOTIC MODULER PLATE	KYP(S,M,L)	
NORM LORDOTIC MODULER PLATE	LRD(S,M,L)	
NORM LATERAL MEDIAL MODULER PLATE	LM(01,02)	
NORM UNIVERSAL-LOCKING SCREW	NULS(70)(30...60)	
NORM INTERSPINOUS U DEVICE	NSUD-SI(08-16)	
NORM LOCKING SCREW	NSLS(60)(20...60)	CERVICAL AND LUMBAR PEEK CAGE - GMDN Code Steril: 60847 Nonsteril: 60762
NORM CANCELLOUS-LOCKING SCREW	NCLS(60...62)(25...40)	
NORM INTERBODY FUSION, LUMBAR PEEK CAGE ANGLED	NVPCA(22...24)(06...12)	
NORM INTERBODY FUSION, LUMBAR PEEK CAGE	NVPCD(22...24)(06...12)	
NORM LUMBAR EXPANDABLE PEEK CAGE	AB-NEPLIF(24)(10)(06...12)	
NORM INTERBODY FUSION, LUMBAR PEEK CAGE ANGLED	AB-NVPCA(22...24)(06...12)	



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NORM INTERBODY FUSION, LUMBAR PEEK CAGE	AB-NVPCD(22...24)(06...12)	
NORM INTERBODY FUSION, LUMBAR PEEK CAGE ANGLED	NVPCA(22...24)(06...16)	
NORM INTERBODY FUSION, LUMBAR PEEK CAGE	NVPCD(22...24)(06...12)	
NORM ALLIGATOR CAGE PLIF	AB-NAC(12)(07...12)	
NORM ALLIGATOR CAGE PLIF	NAC(12)(07...12)	
NORM BANANA CAGE TLIF	AB-NBC(24...32)(07...13)	
NORM EXPANDABLE ALLIGATOR CAGE PLIF	AB-NEPC(10)(07...12)	
NORM EXPANDABLE ALLIGATOR CAGE	NEPC(10)(07...12)	
NORM BANANA CAGE TLIF	NBC(24...32)(07...13)	
NORM EXPANDABLE TITANIUM ALLIGATOR CAGE	NETC(10)(07...13)	
NORM EXPANDABLE BANANA CAGE TLIF	NEBC(28...32)(07...13)	
NORM CERVICAL PEEK CAGE	NCPC(04...08)(12...14)(14...16)	
NORM CERVICAL POLAR PEEK CAGE	NCPC(04...08)(12...14)(14...16)	
NORM CERVICAL TITANIUM CAGE	NCTC(10...20)(10...39)(13...65)	
NORM CERVICAL TITANIUM CAGE ANGLED 6	NCTC(10...20)(10...39)(13...65)(6)	
NORM CERVICAL PEEK CAGE WITH BLADE	NCPCB(4...8)(12...14)(14...16)	
NORM CERVICAL POLAR PEEK CAGE WITH BLADE AND ANATOMICAL SURFACE	NCPCB(4...8)(12...14)(14...16)	
NORM CERVICAL PEEK CAGE ANGLED	NCPC(04...08)(12...14)(14...16)	
NORM POLAR CERVICAL PEEK CAGE	AB-NCPC(04...08)(12...14)(14...16)	
NORM CERVICAL PEEK CAGE	AB-NCPC(04...08)(12...14)(14...16)	
NORM CERVICAL TITANIUM CAGE	AB-NCTC(10...20)(10...39)(13...65)	
NORM CERVICAL TITANIUM CAGE ANGLED 6	AB-NCTC(10...20)(10...39)(13...65)	
CERVICAL TITANIUM EXPANDABLE NORM CAGE	AB-NCTEC(9...13)(235...250)	
NORM CERVICAL TITANIUM EXPANDABLE CAGE	NCTEC(04...08)(12...14)(14...16)	
NORM CERVICAL PEEK CAGE ANGLED	AB-NCPC(04...08)(12...14)(14...16)	
NORM INTERBODY FUSION, LUMBAR PEEK CAGE ANGLED	AB-NVPCA(22...24)(06...12)	
NORM INTERBODY FUSION, LUMBAR PEEK CAGE	AB-NVPCD(22...24)(06...12)	
CERVICAL POLAR PEEK CAGE WITH BLADE AND ANATOMICAL SURFACE	AB-NCPCB(4...8)(12...14)(14...16)	
NORM EXPANDABLE BANANA CAGE TLIF	AB-NEBC(28...32)(07...13)	
POLAR VIVAX CERVICAL CAGE+INSERTS	NPVSC(04...08)(12...14)(14...16)	
POLAR VIVAX CERVICAL CAGE+INSERTS ANGLED	NAPVSC(04...08)(12...14)(14...16)	
NORM LUMBAR EXPANDABLE PEEK CAGE-PLIF	NEPLIFC(24)(10)(06...12)	
NORM LUMBAR EXPANDABLE PEEK CAGE-PLIF	AB-NEPLIFC(24)(10)(06...12)	
TWISTY TLIF PEEK CAGE	NBC(24...32)(08...12)	
NORM BANANA CAGE TLIF	NBC(24...32)(08...12)	
NORM BANANA CAGE TLIF ANGLED	NBCA(24...32)(07...13)(4...8)	
TWISTY TLIF PEEK CAGE ANGLED	NBCA(24...32)(07...13)(4...8)	
NORM CERVICAL PEEK CAGE ANGLED WITH BLADE	NCPAB(4...6)(12...14)(14...16)	
NORM CERVICAL ANTERIOR PLATE	NCAP(17...90)	
NORM CERVICAL ANTERIOR PLATE SCREW	NCAPS(12...20)	
NORM CERVICAL ANTERIOR PLATE SCREW-REVISION	NCAPSR(12...20)	
ZRYTHM LAMINOPLASTY PLATE	NLP(XS,S,M,L,XL)	
ZRYTHM LAMINOPLASTY SCREW	NLPS(5...8)	
ZRYTHM LAMINOPLASTY RESCUE SCREW	NLPRS(5...8)	
INTERVERTEBRAL MOBIL DISC PROSTHESIS	NCD(12...16)(04...09)	
NORM CERVICAL DISC PROSTHESIS PEEK	AB-NCDP(12...16)(05...09)	
NORM CERVICAL DISC PROSTHESIS PEEK	NCDP(12...16)(05...09)	
INTERVERTEBRAL MOBIL DISC PROSTHESIS SILICONE INSERT	AB-NCDSI(12...16)(04...09)	
INTERVERTEBRAL MOBIL DISC PROSTHESIS SILICONE INSERT	NCDSI(12...16)(04...09)	
NORM VERTEBRAL CORPECTOMY LUMBAR TITANIUM CAGE	AB-NVTCD(20...28)(25...100)(34...140)	
NORM VERTEBRAL CORPECTOMY LUMBAR TITANIUM CAGE	NVTCD(20...28)(25...100)(34...140)	
NORM VERTEBRAL CORPECTOMY CAGE ANGLED	NVTCA(20...28)(25...100)(34...140)	
NORM VERTEBRAL CORPECTOMY LUMBAR TITANIUM CAGE ANGLED	AB-NVTCA(20...28)(25...100)(34...140)	
ZEK CORPECTOMY CAGE DISTRACTABLE	NVTCZ(20...28)(25...100)(34...140)	
NORM EXPANDABLE CERVICAL CORPECTOMY TITANIUM CAGE	AB-NCTC(10...20)(10...39)(13...65)	
NORM DISTRACTABLE CERVICAL CORPECTOMY TITANIUM CAGE ANGLED	AB-NCTC(10...20)(10...39)(13...65)(6)	
NORM CERVICAL TITANIUM CORPECTOMY CAGE	NCTC(10...20)(10...39)(13...65)	
NORM CERVICAL TITANIUM CORPECTOMY CAGE ANGLED	NCTC(10...20)(10...39)(13...65)(6)	
NORM CERVICAL CORPECTOMY TITANIUM CAGE EXPANDABLE	AB-NCTEC(9...13)(230...250)	
NORM CORPECTOMY CAGE LOCKING SCREW	NCCLS	
NORM ZEK CORPECTOMY CAGE EXPANDABLE	AB-NVTCZ(20...28)(25...100)(34...140)	
		CERVICAL PLATE SYSTEM-GMDN Code Steril:61324 Nonsteril:61325
		CERVICAL DISC PROSTHESIS-GMDN Code Steril:48164 Nonsteril:61865
		CERVICAL AND LUMBAR CORPECTOMY CAGE - GMDN Code Steril:38161 Nonsteril:57805