

<b>Manufacturer (Üretici)</b>	NORMMED MEDİKAL ve MAKİNA SAN. Ve TİC. LTD. ŞTİ. İvedik Osb 1468 Cad. No:193 ANKARA / TÜRKİYE
<b>Products (Ürünler)</b>	- Spinal Vida Sistemi / Spinal Screw System ( 61324, 61325 ) - Torakolumbar Plak Sistemi / Thoracolumbar Plate System ( 61324, 61325 ) - Servikal ve Lumbar Peek Kafes / Cervical and Lumbar Peek Cage ( 60847, 60762 ) - Servikal Plak Sistemi / Cervical Plate System ( 61324, 61325 ) - Servikal Disk Protezi / Cervical Disc Prosthesis ( 48164, 61865 ) - Servikal ve Lumbar Korpektomi Kafes / Cervical and Lumbar Corpectomy Cage ( 38161, 57805 ) <i>Detaylı ürün listesi, ekli listede verilmiştir./ Detailed product list is given in the attached list.</i>
<b>Classification (Sınıflandırma)</b>	Class IIb, MDD 93/42/EEC Annex IX, Rule 8 (Sınıf IIb, MDD 93/42/EEC Ek IX, Kural 8)
<b>Conformity Assessment Route (Uygunluk Değerlendirme Yolu)</b>	MDD 93/42/EEC Annex II. (Article 4 excluded) MDD 93/42/EEC Ek II. (Madde 4 hariç)

We herewith declare that above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Devices. All supporting documentation is retained under our premises.

*Yukarıdaki ürünlerin Tıbbi Cihazlar için konsey direktifi 93/42/EEC'nin hükümlerini karşıladığını beyan ederiz. Tüm destekleyici dökümanlar üretim tesisimizde saklanmaktadır.*

**Standards Applied (Uygulanan Standardlar)** EN ISO 13485:2016, TS EN ISO 11607-1: 2017, TS EN ISO 11607-2: 2017, TS EN ISO 14971: 2013, TS EN ISO 14630: 2013, TS 1980-1 EN 22768-1: 1995, TS EN ISO 10993-1: 2014, TS EN ISO 10993-3: 2015, TS EN ISO 10993-4: 2017, TS EN ISO 10993-6: 2017, TS EN ISO 10993-7: 2010, TS EN ISO 10993-10: 2014, TS EN ISO 10993-11: 2018, TS EN ISO 10993-12:2013, TS EN ISO 10993-15:2010, TS EN ISO 10993-17:2013, TS EN ISO 10993-18:2010, TS EN ISO 14602: 2012, TS EN ISO 11737-1: 2018, TS EN ISO 11737-2: 2010, TS EN ISO 11135: 2014, TS EN 1041+A1: 2014, TS EN ISO 15223-1: 2016, MEDDEV 2.4/1, MDD/93/42/EEC, 2007/42/EC, 2001/83/EEC, MEDDEV 2.5/5, MEDDEV 2.7/1, MEDDEV 2.7/3, MEDDEV 2.7/4, MEDDEV 2.12/1, MEDDEV 2.12/2, , CE İşareti Yönetmeliği, ASTM F543 - 13e1, ASTM F2193 – 14, ASTM F 1798-13, ASTM F136 – 13, ASTM F1980 – 16, ASTM F382 – 14

<b>Notified Body (Yetkili Belgelendirme Kuruluşu)</b>	Udem Uluslararası Belgelendirme Denetim Eğitim Merkezi San. Ve Tic. Ltd. Şti. / 2292 (Adress: Mutlukent Mah. 2073 Sk. No:10 Ümitköy - Çankaya - ANKARA)
<b>(EC) Certificate(s) (CE Belge(leri))</b>	M.2012.106.1338
<b>Start of CE Marking (CE İşareti Başlangıcı)</b>	20.03.2012
<b>Expired of CE Marking (CE İşareti Bitişi)</b>	14.03.2022
<b>GMDN</b>	61324, 61325, 60847, 60762, 48164, 61865, 38161, 57805

\* *Ürünlerin insan kanı türevi, hayvan kaynaklı doku, fetalat ve lateks içermediğini ve radyasyon yaymadığını beyan ederiz. / We declare that the products do not contain human blood derivatives, tissues of animal origin, phthalate and latex and do not emit radiation.*

**Place, Date of Issue** ANKARA, TÜRKİYE / 17.11.2020

**(Yer ve Yayın Tarihi)**

**Name (İsim)** EMİN GEMİCİ

**Title (Ünvanı)** Company Manager / Şirket Müdürü



Signature (imza)

SPINAL SCREW SYSTEM GMDN – 61324, 61325	
Product Code	Product Name
NMSPA (35...80)(25...100)	NORMMED Polyaxial Screw + Set Screw
NMQSPA(35...80)(25...100)	Normmed Polyaxial Quad Lead Screw + Set Screw
NMCPS (35...80)(25...100)	NORMMED Cannulated Polyaxial Screw + Set Screw
NMQCPS(55...80)(30...60)	Normmed Polyaxial Cannulated Quad Lead Screw + Set Screw
NMSPA(35...80)(25...100)	NORMMED Polyaxial Screw With Holes + Set Screw
NMQSPA(35...80)(30...100)	Normmed Polyaxial Fenestrated Cannulated Quad Lead Screw+ Set Screw
NMSMA(35...80)(25...100)	NORMMED Monoaxial Screw + Set Screw
NMSSS	NORMMED Thoracolumbar Spinal System 6.0 Set Screw 9.90 mm
NMSPRS(35...80)(25...100)	NORMMED Reduction-Poly Type Screw + Set Screw
NMQSPAR(35...80)(25...100)	Normmed Polyaxial Listhesis Quad Lead Screw + Set Screw
NMSMRS(35...80)(25...100)	NORMMED Monoaxial Listesis Screw (Long Type) + Set Screw
NMSR16(04...60)	NORMMED Rod
NMSR16(04...600)	NORMMED Rod Cr-Co
NMSCRR (04...600)	NORMMED Hybrid Rod
NMSAR16(04...25)	NORMMED Anterior Rod
NMSTL (140...180)	NORMMED Transverse Link
NMSTLR (140...180)	NORMMED Transverse Link Rod
NMSTLH	NORMMED Transverse Link Hook
NMSATL (40...60)(60...80)	NORMMED Transverse Link Multiaxial
NMSLCNT (15...40)	NORMMED Lateral Connector
NMNSECNT	NORMMED Lateral Connector Extend For Rod
NMNSOCNT	NORMMED Omniaxial Connector
NMPPH08(05...09)	NORMMED Pedicular Hook Small
NMPHF05(05...07)	NORMMED Pedicle Hook Flexible
NMPLH(05...07)(05...11)	NORMMED Laminar Hook Small Narrow Blade
NMPLHLA7(9...11)	NORMMED Laminar Left Angled 20° Hook Small Narrow Blade
NMPLHRA7(09...11)	NORMMED Laminar Right Angled 20° Hook Small Narrow Blade
NMLHF05(05...07)	NORMMED Laminar Hook Flexible
NMHT3L05(7...11)	NORMMED Hook Type 3L
NMHT3R05(7...11)	NORMMED Hook Type 3R
NMDNR6(050...500)	NORMMED Dynamic Rod
NMDNS(55...75)(30...60)	NORMMED Dynamic Screw
NMSSC(15...20)	NORMMED Sacral Connector
NMSOCNT	NORMMED Omniaxial Sacral Connector
NMSSS(60...70)(30...60)	NORMMED Sacral Screw
NMSIS(70...90)(30...100)	NORMMED Sakroiliac Screw
NMSIS(70...90)(30...100)	NORMMED Sakroiliac Cannulated Screw
NMOPA(35...80)(20...60)	NORMMED Nota Polyaxial Screw
NMOMAS(40...70)x(20...60)	NORMMED Nota Monoaxial Screw
NMOPALS(40...70)(30...60)	NORMMED Nota Polyaxial Listhesis Screw
NMOMALS(40...70)(30...60)	NORMMED Nota Monoaxial Listhesis Screw
NMOTRL(100...200)	NORMMED Nota Transvers Link
NMOTML(40...60)(60...80)	NORMMED Nota Transvers Link Multiaxial
NMOLH(05...07)(05...11)	NORMMED Nota Laminar Hook Small Narrow Blade
NMOLHLA7(09...11)	NORMMED Nota Laminar Left Angled 20° Hook Small Narrow Blade
NMOLHRA7(09...11)	NORMMED Nota Laminar Right Angled 20° Hook Small Narrow Blade
NMOMLH(05...07)(05...07)	NORMMED Nota Multiaxial Laminar Hook
NMOPH08(05...09)	NORMMED Nota Pedicular Hook Small
NMOMPH08(05...07)	NORMMED Nota Multiaxial Pedicular Hook Small
NMOR16(04...60)	NORMMED Nota Rod
NMOLCNT(15...20)	NORMMED Nota Lateral Connector
NMOECNT	NORMMED Nota Lateral Connector For Rod
NMMYSPN(50...70)-(30...50)P	NORMMED Myspine Hemispherical Multiaxial Screw
NMMYSPN(50...70)-(30...60)M	NORMMED Myspine Hemispherical Monoaxial Screw
NMMYSPN(2...5)MRP(S,L,SC)	NORMMED Myspine Modular Rigid Plate Small

NMMYSPN(2,3)MDP(S,L)	NORMMED Myspine Modular Dynamic Plate
NMMYSPN3MDP(S,L)D	NORMMED Myspine Modular Double Dynamic Plate
NMMYSPN3MS(S,L)	NORMMED Myspine Modular Semi-Rigid Plate
NMMYSPNN(50...80)	NORMMED Myspine Hemispherical Nut
NMMYSPN55-(045...170)R	NORMMED Myspine Titanium Rod
NMMYSPN(50...80)TB	NORMMED Myspine Transvers Connector
NMMYSPNCLC(50...80)TB	NORMMED Myspine Cross-Link Connector
NMMYSPN-(CC,ICC,MCC)	NORMMED Myspine Multiaxial Connector Clamp
NMSR155(40...600)	NORMMED Rod
NMPAS(35...50)(20...45)	NORMMED PEDIS Pediatric Polyaxial Screw + Setscrew
NMSNMNMPAS40(35...40)	NORMMED PEDIS Pediatric Spondilolisthesis Polyaxial Screw + Setscrew
NMSNMPPAS(40...50)(35...45)	NORMMED PEDIS Pediatric Spondilolisthesis Polyaxial Screw + Setscrew
NMPPR(40...500)	NORMMED PEDIS Pediatric Rod
NMPTC(40...60)	NORMMED PEDIS Pediatric Transverse Connector
NMPPRC(50...75)(50...60)	NORMMED PEDIS Pediatric Rod Connector
NMPPLC	NORMMED PEDIS Pediatric Lateral Connector
NMPAC	NORMMED PEDIS Pediatric Axial Connector
NMPLH(40...50)(55...75)	NORMMED PEDIS Pediatric Laminar Hook
NMPPH75(55...65)	NORMMED PEDIS Pediatric Pedicle Hook
NMPCSS(35...45)(08...42)	NORMMED Titanium Polyaxial Screw + Set Screw
NMPCSSS	Normmed Posterior Cervical Spinal System 3.5 Set Screw 7.20 mm
NMPCCB(35...45)(06...20)	NORMMED Titanium Cancellous Bone Screw
NMPCHF(S,L)	NORMMED Titanium Occipital Plate
NMPCRWP(S,L)	NORMMED Posterior Cervical Occipital Plate With Rod
NMPCPRD	NORMMED Polyaxial Rod Left-Right
NMPCSCB40(26...40)	NORMMED Titanium Cortical Bone Screw + Set Screw
NMPTOS(35...40)(06...20)	NORMMED Titanium Posterior Cervical Plate Screw
NMPCSP(15...65)	NORMMED Titanium Plate
NMPCLH(45...60)	NORMMED Laminar Hook
NMPCLHA18	NORMMED 18° Degree Angled Hook
NMPCLC(10...12)	NORMMED Lateral Connector
NMPCRC35(35...60)	NORMMED Rod Connector
NMPCTR(12...24)	NORMMED Titanium Rod
NMPCIOS	NORMMED Posterior Cervical Inside Outside Screw + Set Screw
NMPCTL(40...80)	NORMMED Posterior Cervical Transverse Link
NMPCTLH	NORMMED Posterior Cervical Transverse Link Hook
NMOMLH05(05...07)	NOTA Multiaxial Laminar Hook Small Narrow Blade
NMPPH05(05...07)	NORMMED Pedicular Hook Small
NMSATL(20...80)(40...100)	NORMMED Transverse Link Multiaxial
NMYSPN75(30...60)P	Hemispherical Multiaxial Screw
NMYSPN-TBA (20...80)x(10...80)	MYSPINE Transversal Connector Multiaxial
NMLM	NORMMED Lateral Medial Modular Plate
NMKYP(S,M,L)	NORMMED Kyphotic Modular Plate
NMLRD(S,M,L)	NORMMED Lordotic Modular Plate
NMSAC(S,M,L)	NORMMED Sacrum Modular Plate
NMSMA(65...75)(30...60)	NORMMED Monoaxial Screw + Set Screw
NMSMRS(45...75)(25...60)	NORMMED Monoaxial Listesis Screw (Long Type) + Set Screw
NMSPA(65...75)60	NORMMED Polyaxial Screw + Set Screw
NMSPRS(45...75)(25...60)	NORMMED Reduction-Poly Type Screw + Set Screw
NMPCHF(S,M,L)	Titanium Occipital Plate Medium
NMPCLH04(5...7)	Laminar Hook
NMPCORA	Titanium Occipitocervical Rod 45° Angled
NMSPA75(60...100)	NORMMED Polyaxial Screw + Set Screw
NMOPAS	NOTA Polyaxial Screw
NMPTOS35(18...20)	Titanium Posterior Cervical Plate Screw
NMPCSS35(26...32)	Titanium Polyaxial Screw + Set Screw
NMSPAK (35...80)(20...100)	NORMMED Polyaxial Dual Threaded Screw + Set Screw
NMSPAKR (35...80)(20...100)	NORMMED Polyaxial Listhesis Dual Threaded Screw + Set Screw
NMSPAKC(55...80)(30...60)	Normmed Polyaxial Cannulated Dual Threaded Screw + Set Screw

## Declaration of Conformity (Uygunluk Beyanı)

NMSPAKH(55...80)(30...60)	Normmed Polyaxial Fenestrated Cannulated Dual Threaded Screw + Set Screw
NMSMAK(35...80)(30...100)	NORMMED Monoaxial Self Tapping Screw + Set Screw
NMSMAKR(35...80)(30...100)	NORMMED Monoaxial Listhesis Self Tapping Screw + Set Screw
NMSPRSS(50...80)(40...80)	NORMMED Thoracolumbar Posterior Polyaxial Screw, Titanium, Sacroiliac + Set Screw
NMOPASK(30...75)(20...60)	NOTA Polyaxial Self Tapping Screw
NMOMASK(45...65)(25...60)	NOTA Monoaxial Self Tapping Screw
MOPALSS(45...70)(30...60)	NOTA Thoracolumbar Posterior Polyaxial Screw, Titanium, Sacroiliac (Locking Part and Nut)
NMJW(4...8)813	Joint Wing Facet Distractor Implant
NMJFFS(45...50)(25...50)	Joint Fix Facet Screw
NMCDPS(12...20)	NORMMED Cervical Disc Prosthesis Screw
NMCPRC3535	NORMMED Rod Connector 3,5-3,5
NMPXR(030...480)	Pedifix Rod
NMPXCCR(030...480)	Pedifix Cr-Co Rod
NMPXMC(12...24)	Pedifix Monoblock Cross Connector
NMPXPC(24...45)(30...60)	Pedifix Polyaxial Cross Connector (Small, Medium, Large, X-Large)
NMPXMS(40...75)(20...60)	Pedifix Monoaxial Screw
NMPXPS(40...75)(20...60)	Pedifix Polyaxial Screw
NMPXPSSS	Normmed Pediatric Spinal System 4.5 Set Screw 8.40 mm
NMPXPCS(40...75)(20...70)	Pedifix Pediatric Polyaxial Cannulated Screw
NMPXPH(S,L)	Pedifix Pedicle Hook (Small, Large)
NMPXLH(S,M,L)	Pedifix Laminar Hook (Small, Medium, Large)
NMPXLHA	Pedifix Laminar Hook Angled Blade
NMPXLHR	Pedifix Thoracic Laminar Hook Ramped
NMPXLHE	Pedifix Extended Body Laminar Hook
NMPXTH(L,R)	Pedifix Transverse Proses Hook (Left,Right)
NMPXTHO(L,R)	Pedifix Thoracic Hook Offset (Left,Right)
NMPXSH(L,R)	Pedifix Supralaminar Thoracic Hook (Left,Right)
NMPXDSC(S,L)	Pedifix Dual Staple Caudal (Small, Large)
NMPXDSR(S,L)	Pedifix Dual Staple Rostral (Small, Large)
NMPXPDC(S,L) (45)(45...60)	Pedifix Rod To Rod Connector (Small, Large)
NMPXPDC4535	Pedifix Rod To Rod Connector
NMPXOC(30...70)	Pedifix Offset Connector
NMPXEC(S,L)	Pedifix Extended Connector (Small, Large)(30...60)
NMPXIC00	Pedifix Parallel Connector
NMPXIC(15...45)	Pedifix Iliac Connector
NMPXSS	Pedifix Single Staple
NMPXPRS(45...60)(20...50)	Pedifix Polyaxial Listhesis Screw
NMLMIS(40...80)(20...100)	Levissi MIS Dual Lead Cannulated Polyaxial Screw
NMLMISR (Ø6)(40...120)C	Normmed MIS Ø6.0 Curved Rod
NMLMISR(Ø6)(40...200)S	Normmed MIS Ø6.0 Straight Rod
<b>THORACOLUMBAR PLATE SYSTEM GMDN – 61324, 61325</b>	
<b>Product Code</b>	<b>Product Name</b>
NMSAP(L,R)(23...25)	NORMMED Anterior Agrafe Plate (Double Nail)
NMSATB(23...25)(15...17)	NORMMED Anterior Transverse Connector
NMSLP(70...120)U	NORMMED Anterior Lumbar Locking Plate
NMLP(40...120)U	NORMMED Anterior Lumbar Locking Plate
NMLST	NORMMED Locking SET Screw
NMLN	NORMMED Locking Nut
NMULS(70)(30...60)	NORMMED Anterior Universal-Locking Screw
NMSLS(60)(20...60)	NORMMED Anterior SELF - Locking Screw
NMCLS(60...62)(25...40)	NORMMED Anterior Cancellous-Locking Screw
NMSUD-SI(08-16)	NORMMED Interspinous U Device
<b>CERVICAL AND LUMBAR PEEK CAGE GMDN – 60847, 60762</b>	
<b>Product Code</b>	<b>Product Name</b>
NMVPCA(22...24)(06...12)	NORMMED Interbody Fusion, Lumbar PEEK Cage Angled
NMAC(12)(07...12)	NORMMED Alligator Cage

NMEPC(10)(07...12)	NORMMED Expandable Alligator Cage
NMXPC(08...16)(18)(40...55)(00)	NORMMED Lomber Peek Kafes Xlif
NMXPC(08...16)(18)(40...55)(10)	NORMMED Lomber PEEK Cage Xlif Lordotic 10° Angled
NMBC(24...32)(07...13)	NORMMED Tlif PEEK Cage
NMBCA(24...32)(07...13)	NORMMED Tlif PEEK Cage 4° Angled
NMEBC(28...32)(07...13)	NORMMED Expandable Tlif PEEK Cage
NMALC(25..29)(35..40)(10..20)(04..14)	NORMMED Normmed Alif Cage
NMALCS(20..30)	NORMMED Alif Locking Screw
NMALCSF(20...30)	Normmed Alif Cage Fine Tip Screw
NMPCB(4..8)(12...14)(14...16)	NORMMED Cervical PEEK Cage Anatomical Surface With Knife and Anatomical Surface
NMPC(04...08)(12...14)(14...16)	NORMMED Cervical PEEK Cage Anatomical Surface
NMPVSC(04...08)(12...14)(14...16)	NORMMED POLAR VIVAX Cervical PEEK Cage + Inserts
NMAPVSC(04...08)(12...14)(4)	NORMMED POLAR VIVAX Cervical PEEK Cage + Inserts Angled
NMEPLIFC(24)(10)(06...12)	NORMMED Lumbar Expandable PEEK Cage - Plif
NMBC(24...32)(08...12)	TWISTY Tlif PEEK Cage
NMBCA(24...32)(07...13)(4...8)	TWISTY Tlif PEEK Cage 4° Angled
NMBC(24...32)(07...11)	TWISTY Tlif PEEK Cage
NMBCA(24...32)(07...13)(4)	TWISTY Tlif PEEK Cage 4° Angled
NMBC(24...32)(13)	TWISTY Tlif PEEK Cage
<b>CERVICAL AND LUMBAR TITANIUM CAGE- GMDN- 38161</b>	
<b>Product Code</b>	<b>Product Name</b>
NMPLTC (10...16)(07...13)	Normmed Plif Titanium Cage
NMPTCE (10...16)(07...13)	Normmed Plif Titanium Expandable Cage
NMTTC (10...16)(07...13)	Normmed Tlif Titanium Cage
NMTTCE (10...16)(07...13)	Normmed R-Tlif Titanium Expandable Cage
NMCRTC (04...09)(12...20)	Normmed Cervical Titanium Cage
NMCTCE (04...09) (12...20)	Normmed Cervical Titanium Expandable Cage
<b>CERVICAL PLATE SYSTEM GMDN – 61324, 61325</b>	
<b>Product Code</b>	<b>Product Name</b>
NMCAP(17...90)	NORMMED Cervical Anterior Plate
NMCAPS(12...20)	NORMMED Cervical Anterior Plate Screw
NMCAPSR(12...20)	NORMMED Cervical Anterior Plate Screw - Revision
NMLP(XS,S,M,L,XL)	ZRYTHM Laminoplasty Plate
NMLPS(5...8)	ZRYTHM Laminoplasty Screw
NMLPRS	ZRYTHM Laminoplasty Rescue Screw
<b>CERVICAL DISC PROSTHESIS GMDN –48164, 61865</b>	
<b>Product Code</b>	<b>Product Name</b>
NMCD(12...16)-(04...09)	Cervical Disc Prosthesis
NMCDP(12...16)(04...09)	NORMMED Cervical Disc Prosthesis PEEK
NMCDSI(12...16)(04...09)	NORMMED Cervical Disc Prosthesis Silicone Insert
NMCDOP(12...)(04...09)	Normmed Cervical One Part Disc Prosthesis
<b>CERVICAL AND LUMBAR CORPECTOMY CAGE GMDN – 38161, 57805</b>	
<b>Product Code</b>	<b>Product Name</b>
NMVTCD(20...28)(25...100)(34...140)	NORMMED Vertebral Corpectomy Cage
NMVTCA(20...28)(25...100)(34...140)	NORMMED Vertebral Corpectomy Cage Angled
NMCTC(10...20)(10...39)(13...65)(6)	NORMMED Cervical Titanium Corpectomy Cage
NMCCLS	NORMMED Corpectomy Cage Locking Screw
NMVT CZ(20...28)(25...100)(34...140)	ZEK Corpectomy Cage Distractable