

Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale

nr. 74 din 26.12.2023

Solicitantul **FPC "SOGNO" S.R.L.**, cu sediul MD-2028, mun. Chișinău, str. Academiei, 2, tel.: (022) 72-75-25/
069501992, fax: (022) 73-83-42, e-mail: sognomd@gmail.com, pungaala@gmail.com.

solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Conform Anexei nr.3 "Lista dispozitivelor medicale Changzhou Toolmed Medical Instruments Co. (casa IIb)"

Se anexează următoarele acte:

1. Certificat CE
2. Declarație de Conformitate.
3. Scrisoarea autorizată a producătorului.
4. Declarație pe propria răspundere.
5. Lista dispozitivelor medicale.

Data: 26.12.2023

Semnătura



Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	Accept
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	NR 8373 din 03.01.2024
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Valentina Balaban șef-sect. not
Semnătura persoanei responsabile	

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **FPC "SOGNO" SRL**, cu sediul m.Chișinău, str. Academiei nr.2, Republica Moldova,
declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la
falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale:

**Conform Anexei nr.3 "Lista dispozitivelor medicale Changzhou Toolmed Medical Instruments Co.
(clasa IIb)"**

Sunt autentice și corespund realității.

Iarovoi Petru, Director



Data: 26.12.2023



Changzhou Toolmed Medical Instruments Co., Ltd.

No. 23 Wangcai Road, Luoxi Town

Xinbei District, Changzhou, 213000

Jiangsu, P.R. of China

0086 (519) 83407182

www.cztoolmed.com

AUTHORIZATION LETTER

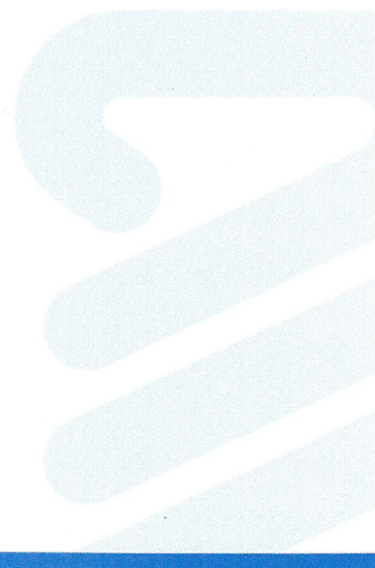
We, Changzhou Toolmed Medical Instruments Co., Ltd., based in No.23 Wangcai Road, Airport Industrial Park, Xinbei District, 213000, Changzhou, Jiangsu, P.R. of China, assign FPC "SOGNO" SRL, based at No 2 Academiei str., Chisinau, Republic of Moldova, as authorized representative in correspondence with the conditions of Directive 93/42/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Changzhou, China

Date: 25.10.2023

Signature:





Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 102458 0002 Rev. 00

Manufacturer:

**Changzhou Toolmed
Medical Instruments Co., LTD**

No. 51 Pengjia village
Luoxi town, Xinbei area
213001 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies): Lockable Intramedullary Nails,
Bone Plates, Bone Screws,
General Spine System**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH18137601

Valid from: 2019-10-08

Valid until: 2024-05-26

Date, 2019-10-08

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT



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Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
 (Devices in Class IIa, IIb or III)

No. G1 102458 0002 Rev. 00

Facility(ies):

**Changzhou Toolmed Medical Instruments Co., LTD
 No. 51 Pengjia village, Luoxi town, Xinbei area,
 213001 Changzhou, Jiangsu, PEOPLE'S REPUBLIC
 OF CHINA**

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFIKAT ◆ CERTIFICADO ◆ CERTIFICAT





Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 102458 0003 Rev. 00

Manufacturer:

**Changzhou Toolmed
Medical Instruments Co., LTD**
No. 23 Wangcai Road, Airport Industrial Park
Xinbei District
213000 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

**This Confirmation Statement
is only valid in combination
with the following
EC Certificate (MDD):**

G1 102458 0002 Rev. 00

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer
data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for
placing devices on the market and putting into service apply. For details and confirmation statement
validity see: www.tuvsud.com/ps-cert?q=cert:GCQ_102458_0003_Rev.00

Report No.:

SH22137601

Valid until:

2024-05-26

Christoph Dicks
Head of Certification/Notified Body

Issue Date: 2023-03-22





Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 102458 0003 Rev. 00

**Product Category(ies): Lockable Intramedullary Nails,
Bone Plates, Bone Screws,
General Spine System**

Description of Change:

Change the site from "No. 51 Pengjia village Luoxi Town, Xinbei area 203001 Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA" to "No.23, Wangcai Road, Airport Industrial Park, Xinbei District, 213000, Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA".



CE Technical File Bone Screws	File No: TM-TCF-03_6
	Rev. No: A/0

Declaration of Conformity

Manufacturer: **Changzhou Toolmed Medical Instruments Co.,LTD.**
Address: No.23, Wangcai Road, Airport Industrial Park,
Xinbei District, 213000, Changzhou, Jiangsu, China

European Representative: Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd,2595AA, The Hague, Netherlands

Product Name: Bone Screws

Models: Please refer CE Product list (Annex No.1)

GMDN Code: 56642

Classification (MDD, Annex IX): **IIb / Rule 8**

Conformity Assessment Route: **Annex II.3**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65,
80339 München, Germany

NB Identification number: 0123

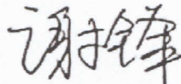
(EC) Certificate(s): G1 102458 0002 REV.00, GCQ 102458 0003 REV.00

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2019-10-08

Place, Date of Issue: **Changzhou China, 2023-10-18**

Signature:



Name: Xie Feng

Position: Management Representative



ANNEX No. 1

Ref. No.	Description	Material	Specification	Class	GMDN Code
030012030016	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=16, L1=5	IIb	56642
030012030017	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=17, L1=6	IIb	56642
030012030018	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=18, L1=6	IIb	56642
030012030019	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=19, L1=6	IIb	56642
030012030020	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=20, L1=7	IIb	56642
030012030021	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=21, L1=7	IIb	56642
030012030022	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=22, L1=7	IIb	56642
030012030023	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=23, L1=8	IIb	56642
030012030024	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=24, L1=8	IIb	56642
030012030025	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=25, L1=8	IIb	56642
030012030026	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=26, L1=9	IIb	56642
030012030027	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=27, L1=9	IIb	56642
030012030028	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=28, L1=9	IIb	56642
030012030029	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=29, L1=10	IIb	56642
030012030030	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=30, L1=10	IIb	56642
030012030032	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=32, L1=11	IIb	56642
030012030034	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=34, L1=11	IIb	56642
030012030036	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=36, L1=12	IIb	56642
030012030038	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=38, L1=12	IIb	56642
030012030040	3.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=40, L1=12	IIb	56642
030012130016	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=16, L2=8	IIb	56642
030012130017	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=17, L2=8	IIb	56642
030012130018	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=18, L2=9	IIb	56642
030012130019	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=19, L2=9	IIb	56642
030012130020	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=20, L2=10	IIb	56642
030012130021	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=21, L2=10	IIb	56642
030012130022	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=22, L2=11	IIb	56642
030012130023	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=23, L2=11	IIb	56642
030012130024	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=24, L2=12	IIb	56642
030012130025	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=25, L2=12	IIb	56642
030012130026	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=26, L2=13	IIb	56642
030012130027	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=27, L2=13	IIb	56642
030012130028	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=28, L2=14	IIb	56642
030012130029	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=29, L2=14	IIb	56642
030012130030	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=30, L2=15	IIb	56642
030012130032	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=32, L2=15	IIb	56642
030012130034	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=34, L2=17	IIb	56642
030012130036	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=36, L2=17	IIb	56642
030012130038	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=38, L2=19	IIb	56642
030012130040	3.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=40, L2=19	IIb	56642



**CE Technical File
Bone Screws**

File No: TM-TCF-03_6

Rev. No: A/0

030012130000	Washer Ø6.5	TC4	Ø6.5mm	IIb	56642
030012340022	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=22, L1=8	IIb	56642
030012340024	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=24, L1=8	IIb	56642
030012340026	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=26, L1=9	IIb	56642
030012340028	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=28, L1=9	IIb	56642
030012340030	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=30, L1=10	IIb	56642
030012340032	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=32, L1=10	IIb	56642
030012340034	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=34, L1=12	IIb	56642
030012340036	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=36, L1=12	IIb	56642
030012340038	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=38, L1=13	IIb	56642
030012340040	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=40, L1=13	IIb	56642
030012340042	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=42, L1=14	IIb	56642
030012340044	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=44, L1=14	IIb	56642
030012340046	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=46, L1=16	IIb	56642
030012340048	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=48, L1=16	IIb	56642
030012340050	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=50, L1=17	IIb	56642
030012340052	4.0mm Cannulated Screw (Threaded Length = 1/3 Screw Length)	TC4	L=52, L1=17	IIb	56642
030012440022	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=22, L2=11	IIb	56642
030012440024	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=24, L2=12	IIb	56642
030012440026	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=26, L2=13	IIb	56642
030012440028	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=28, L2=14	IIb	56642
030012440030	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=30, L2=15	IIb	56642
030012440032	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=32, L2=16	IIb	56642
030012440034	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=34, L2=17	IIb	56642
030012440036	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=36, L2=18	IIb	56642
030012440038	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=38, L2=19	IIb	56642
030012440040	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=40, L2=20	IIb	56642
030012440042	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=42, L2=21	IIb	56642
030012440044	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=44, L2=22	IIb	56642
030012440046	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=46, L2=23	IIb	56642
030012440048	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=48, L2=24	IIb	56642
030012440050	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=50, L2=25	IIb	56642
030012440052	4.0mm Cannulated Screw (Threaded Length = 1/2 Screw Length)	TC4	L=52, L2=26	IIb	56642
030012340000	Washer Ø7	TC4	Ø7mm	IIb	56642
030012145022	4.5 Cannulated Screw	TC4	L=22	IIb	56642
030012145024	4.5 Cannulated Screw	TC4	L=24	IIb	56642
030012145026	4.5 Cannulated Screw	TC4	L=26	IIb	56642
030012145028	4.5 Cannulated Screw	TC4	L=28	IIb	56642
030012145030	4.5 Cannulated Screw	TC4	L=30	IIb	56642
030012145032	4.5 Cannulated Screw	TC4	L=32	IIb	56642
030012145034	4.5 Cannulated Screw	TC4	L=34	IIb	56642
030012145036	4.5 Cannulated Screw	TC4	L=36	IIb	56642
030012145038	4.5 Cannulated Screw	TC4	L=38	IIb	56642



**CE Technical File
Bone Screws**

File No: TM-TCF-03_6

Rev. No: A/0

030012145040	4.5 Cannulated Screw	TC4	L=40	IIb	56642
030012145042	4.5 Cannulated Screw	TC4	L=42	IIb	56642
030012145044	4.5 Cannulated Screw	TC4	L=44	IIb	56642
030012145046	4.5 Cannulated Screw	TC4	L=46	IIb	56642
030012145048	4.5 Cannulated Screw	TC4	L=48	IIb	56642
030012145050	4.5 Cannulated Screw	TC4	L=50	IIb	56642
030012145052	4.5 Cannulated Screw	TC4	L=52	IIb	56642
030012145054	4.5 Cannulated Screw	TC4	L=54	IIb	56642
030012145056	4.5 Cannulated Screw	TC4	L=56	IIb	56642
030012145058	4.5 Cannulated Screw	TC4	L=58	IIb	56642
030012145060	4.5 Cannulated Screw	TC4	L=60	IIb	56642
030012145000	Washer Ø10	TC4	Ø10mm	IIb	56642
030012073050	7.3 Cannulated Screw (Threaded Length 16mm)	TC4	L=50, 16mm	IIb	56642
030012073055	7.3 Cannulated Screw (Threaded Length 16mm)	TC4	L=55, 16mm	IIb	56642
030012073060	7.3 Cannulated Screw (Threaded Length 16mm)	TC4	L=60, 16mm	IIb	56642
030012073065	7.3 Cannulated Screw (Threaded Length 16mm)	TC4	L=65, 16mm	IIb	56642
030012073070	7.3 Cannulated Screw (Threaded Length 16mm)	TC4	L=70, 16mm	IIb	56642
030012073075	7.3 Cannulated Screw (Threaded Length 16mm)	TC4	L=75, 16mm	IIb	56642
030012073080	7.3 Cannulated Screw (Threaded Length 16mm)	TC4	L=80, 16mm	IIb	56642
030012073085	7.3 Cannulated Screw (Threaded Length 16mm)	TC4	L=85, 16mm	IIb	56642
030012073090	7.3 Cannulated Screw (Threaded Length 16mm)	TC4	L=90, 16mm	IIb	56642
030012073095	7.3 Cannulated Screw (Threaded Length 16mm)	TC4	L=95, 16mm	IIb	56642
030012073100	7.3 Cannulated Screw (Threaded Length 16mm)	TC4	L=100, 16mm	IIb	56642
030012073105	7.3 Cannulated Screw (Threaded Length 16mm)	TC4	L=105, 16mm	IIb	56642
030012073110	7.3 Cannulated Screw (Threaded Length 16mm)	TC4	L=110, 16mm	IIb	56642
030012073115	7.3 Cannulated Screw (Threaded Length 16mm)	TC4	L=115, 16mm	IIb	56642
030012173060	7.3 Cannulated Screw (Threaded Length 32mm)	TC4	L=60, 32mm	IIb	56642
030012173065	7.3 Cannulated Screw (Threaded Length 32mm)	TC4	L=65, 32mm	IIb	56642
030012173070	7.3 Cannulated Screw (Threaded Length 32mm)	TC4	L=70, 32mm	IIb	56642
030012173075	7.3 Cannulated Screw (Threaded Length 32mm)	TC4	L=75, 32mm	IIb	56642
030012173080	7.3 Cannulated Screw (Threaded Length 32mm)	TC4	L=80, 32mm	IIb	56642
030012173085	7.3 Cannulated Screw (Threaded Length 32mm)	TC4	L=85, 32mm	IIb	56642
030012173090	7.3 Cannulated Screw (Threaded Length 32mm)	TC4	L=90, 32mm	IIb	56642
030012173095	7.3 Cannulated Screw (Threaded Length 32mm)	TC4	L=95, 32mm	IIb	56642
030012173100	7.3 Cannulated Screw (Threaded Length 32mm)	TC4	L=100, 32mm	IIb	56642
030012173105	7.3 Cannulated Screw (Threaded Length 32mm)	TC4	L=105, 32mm	IIb	56642
030012173110	7.3 Cannulated Screw (Threaded Length 32mm)	TC4	L=110, 32mm	IIb	56642
030012173000	Washer Ø13	TC4	Ø13mm	IIb	56642
030012124010	HB2.4 Headless Cannulated Screw (II)	TC4	L=10, L1=4	IIb	56642
030012124011	HB2.4 Headless Cannulated Screw (II)	TC4	L=11, L1=4	IIb	56642
030012124012	HB2.4 Headless Cannulated Screw (II)	TC4	L=12, L1=4	IIb	56642
030012124013	HB2.4 Headless Cannulated Screw (II)	TC4	L=13, L1=4	IIb	56642
030012124014	HB2.4 Headless Cannulated Screw (II)	TC4	L=14, L1=4	IIb	56642



**CE Technical File
Bone Screws**

File No: TM-TCF-03_6

Rev. No: A/0

030012124015	HB2.4 Headless Cannulated Screw (II)	TC4	L=15, L1=4	IIb	56642
030012124016	HB2.4 Headless Cannulated Screw (II)	TC4	L=16, L1=4	IIb	56642
030012124017	HB2.4 Headless Cannulated Screw (II)	TC4	L=17, L1=4	IIb	56642
030012124018	HB2.4 Headless Cannulated Screw (II)	TC4	L=18, L1=4	IIb	56642
030012124019	HB2.4 Headless Cannulated Screw (II)	TC4	L=19, L1=4	IIb	56642
030012124020	HB2.4 Headless Cannulated Screw (II)	TC4	L=20, L1=4	IIb	56642
030012124021	HB2.4 Headless Cannulated Screw (II)	TC4	L=21, L1=4	IIb	56642
030012124022	HB2.4 Headless Cannulated Screw (II)	TC4	L=22, L1=4	IIb	56642
030012124023	HB2.4 Headless Cannulated Screw (II)	TC4	L=23, L1=4	IIb	56642
030012124024	HB2.4 Headless Cannulated Screw (II)	TC4	L=24, L1=5	IIb	56642
030012124025	HB2.4 Headless Cannulated Screw (II)	TC4	L=25, L1=5	IIb	56642
030012124026	HB2.4 Headless Cannulated Screw (II)	TC4	L=26, L1=5	IIb	56642
030012124027	HB2.4 Headless Cannulated Screw (II)	TC4	L=27, L1=6	IIb	56642
030012124028	HB2.4 Headless Cannulated Screw (II)	TC4	L=28, L1=6	IIb	56642
030012124029	HB2.4 Headless Cannulated Screw (II)	TC4	L=29, L1=6	IIb	56642
030012124030	HB2.4 Headless Cannulated Screw (II)	TC4	L=30, L1=7	IIb	56642
030012124032	HB2.4 Headless Cannulated Screw (II)	TC4	L=32, L1=7	IIb	56642
030012124034	HB2.4 Headless Cannulated Screw (II)	TC4	L=34, L1=8	IIb	56642
030012124036	HB2.4 Headless Cannulated Screw (II)	TC4	L=36, L1=9	IIb	56642
030012124038	HB2.4 Headless Cannulated Screw (II)	TC4	L=38, L1=9	IIb	56642
030012124040	HB2.4 Headless Cannulated Screw (II)	TC4	L=40, L1=10	IIb	56642
030012224016	HB2.4 Headless Cannulated Screw (II)	TC4	L=16, L2=5	IIb	56642
030012224017	HB2.4 Headless Cannulated Screw (II)	TC4	L=17, L2=6	IIb	56642
030012224018	HB2.4 Headless Cannulated Screw (II)	TC4	L=18, L2=6	IIb	56642
030012224019	HB2.4 Headless Cannulated Screw (II)	TC4	L=19, L2=7	IIb	56642
030012224020	HB2.4 Headless Cannulated Screw (II)	TC4	L=20, L2=7	IIb	56642
030012224021	HB2.4 Headless Cannulated Screw (II)	TC4	L=21, L2=8	IIb	56642
030012224022	HB2.4 Headless Cannulated Screw (II)	TC4	L=22, L2=8	IIb	56642
030012224023	HB2.4 Headless Cannulated Screw (II)	TC4	L=23, L2=8	IIb	56642
030012224024	HB2.4 Headless Cannulated Screw (II)	TC4	L=24, L2=8	IIb	56642
030012224025	HB2.4 Headless Cannulated Screw (II)	TC4	L=25, L2=8	IIb	56642
030012224026	HB2.4 Headless Cannulated Screw (II)	TC4	L=26, L2=10	IIb	56642
030012224027	HB2.4 Headless Cannulated Screw (II)	TC4	L=27, L2=10	IIb	56642
030012224028	HB2.4 Headless Cannulated Screw (II)	TC4	L=28, L2=10	IIb	56642
030012224029	HB2.4 Headless Cannulated Screw (II)	TC4	L=29, L2=10	IIb	56642
030012224030	HB2.4 Headless Cannulated Screw (II)	TC4	L=30, L2=12	IIb	56642
030012224032	HB2.4 Headless Cannulated Screw (II)	TC4	L=32, L2=12	IIb	56642
030012224034	HB2.4 Headless Cannulated Screw (II)	TC4	L=34, L2=14	IIb	56642
030012224036	HB2.4 Headless Cannulated Screw (II)	TC4	L=36, L2=14	IIb	56642
030012224038	HB2.4 Headless Cannulated Screw (II)	TC4	L=38, L2=16	IIb	56642
030012224040	HB2.4 Headless Cannulated Screw (II)	TC4	L=40, L2=16	IIb	56642
030012230010	HB3.0 Headless Cannulated Screw (II)	TC4	L=10, L1=4	IIb	56642
030012230011	HB3.0 Headless Cannulated Screw (II)	TC4	L=11, L1=4	IIb	56642



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030012230012	HB3.0 Headless Cannulated Screw (II)	TC4	L=12, L1=4	IIb	56642
030012230013	HB3.0 Headless Cannulated Screw (II)	TC4	L=13, L1=4	IIb	56642
030012230014	HB3.0 Headless Cannulated Screw (II)	TC4	L=14, L1=4	IIb	56642
030012230015	HB3.0 Headless Cannulated Screw (II)	TC4	L=15, L1=4	IIb	56642
030012230016	HB3.0 Headless Cannulated Screw (II)	TC4	L=16, L1=4	IIb	56642
030012230017	HB3.0 Headless Cannulated Screw (II)	TC4	L=17, L1=4	IIb	56642
030012230018	HB3.0 Headless Cannulated Screw (II)	TC4	L=18, L1=4	IIb	56642
030012230019	HB3.0 Headless Cannulated Screw (II)	TC4	L=19, L1=4	IIb	56642
030012230020	HB3.0 Headless Cannulated Screw (II)	TC4	L=20, L1=4	IIb	56642
030012230021	HB3.0 Headless Cannulated Screw (II)	TC4	L=21, L1=4	IIb	56642
030012230022	HB3.0 Headless Cannulated Screw (II)	TC4	L=22, L1=4	IIb	56642
030012230023	HB3.0 Headless Cannulated Screw (II)	TC4	L=23, L1=4	IIb	56642
030012230024	HB3.0 Headless Cannulated Screw (II)	TC4	L=24, L1=5	IIb	56642
030012230025	HB3.0 Headless Cannulated Screw (II)	TC4	L=25, L1=5	IIb	56642
030012230026	HB3.0 Headless Cannulated Screw (II)	TC4	L=26, L1=5	IIb	56642
030012230027	HB3.0 Headless Cannulated Screw (II)	TC4	L=27, L1=6	IIb	56642
030012230028	HB3.0 Headless Cannulated Screw (II)	TC4	L=28, L1=6	IIb	56642
030012230029	HB3.0 Headless Cannulated Screw (II)	TC4	L=29, L1=6	IIb	56642
030012230030	HB3.0 Headless Cannulated Screw (II)	TC4	L=30, L1=7	IIb	56642
030012230032	HB3.0 Headless Cannulated Screw (II)	TC4	L=32, L1=7	IIb	56642
030012230034	HB3.0 Headless Cannulated Screw (II)	TC4	L=34, L1=8	IIb	56642
030012230036	HB3.0 Headless Cannulated Screw (II)	TC4	L=36, L1=9	IIb	56642
030012230038	HB3.0 Headless Cannulated Screw (II)	TC4	L=38, L1=9	IIb	56642
030012230040	HB3.0 Headless Cannulated Screw (II)	TC4	L=40, L1=10	IIb	56642
030012330016	HB3.0 Headless Cannulated Screw (II)	TC4	L=16, L2=5	IIb	56642
030012330017	HB3.0 Headless Cannulated Screw (II)	TC4	L=17, L2=6	IIb	56642
030012330018	HB3.0 Headless Cannulated Screw (II)	TC4	L=18, L2=6	IIb	56642
030012330019	HB3.0 Headless Cannulated Screw (II)	TC4	L=19, L2=7	IIb	56642
030012330020	HB3.0 Headless Cannulated Screw (II)	TC4	L=20, L2=7	IIb	56642
030012330021	HB3.0 Headless Cannulated Screw (II)	TC4	L=21, L2=8	IIb	56642
030012330022	HB3.0 Headless Cannulated Screw (II)	TC4	L=22, L2=8	IIb	56642
030012330023	HB3.0 Headless Cannulated Screw (II)	TC4	L=23, L2=8	IIb	56642
030012330024	HB3.0 Headless Cannulated Screw (II)	TC4	L=24, L2=8	IIb	56642
030012330025	HB3.0 Headless Cannulated Screw (II)	TC4	L=25, L2=8	IIb	56642
030012330026	HB3.0 Headless Cannulated Screw (II)	TC4	L=26, L2=10	IIb	56642
030012330027	HB3.0 Headless Cannulated Screw (II)	TC4	L=27, L2=10	IIb	56642
030012330028	HB3.0 Headless Cannulated Screw (II)	TC4	L=28, L2=10	IIb	56642
030012330029	HB3.0 Headless Cannulated Screw (II)	TC4	L=29, L2=10	IIb	56642
030012330030	HB3.0 Headless Cannulated Screw (II)	TC4	L=30, L2=12	IIb	56642
030012330032	HB3.0 Headless Cannulated Screw (II)	TC4	L=32, L2=12	IIb	56642
030012330034	HB3.0 Headless Cannulated Screw (II)	TC4	L=34, L2=14	IIb	56642
030012330036	HB3.0 Headless Cannulated Screw (II)	TC4	L=36, L2=14	IIb	56642
030012330038	HB3.0 Headless Cannulated Screw (II)	TC4	L=38, L2=16	IIb	56642



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030012330040	HB3.0 Headless Cannulated Screw (II)	TC4	L=40, L2=16	IIb	56642
030012435014	HB3.5 Headless Cannulated Screw (II)	TC4	L=14, L1=4	IIb	56642
030012435015	HB3.5 Headless Cannulated Screw (II)	TC4	L=15, L1=4	IIb	56642
030012435016	HB3.5 Headless Cannulated Screw (II)	TC4	L=16, L1=4	IIb	56642
030012435017	HB3.5 Headless Cannulated Screw (II)	TC4	L=17, L1=4	IIb	56642
030012435018	HB3.5 Headless Cannulated Screw (II)	TC4	L=18, L1=4	IIb	56642
030012435019	HB3.5 Headless Cannulated Screw (II)	TC4	L=19, L1=4	IIb	56642
030012435020	HB3.5 Headless Cannulated Screw (II)	TC4	L=20, L1=4	IIb	56642
030012435021	HB3.5 Headless Cannulated Screw (II)	TC4	L=21, L1=4	IIb	56642
030012435022	HB3.5 Headless Cannulated Screw (II)	TC4	L=22, L1=4	IIb	56642
030012435023	HB3.5 Headless Cannulated Screw (II)	TC4	L=23, L1=4	IIb	56642
030012435024	HB3.5 Headless Cannulated Screw (II)	TC4	L=24, L1=5	IIb	56642
030012435025	HB3.5 Headless Cannulated Screw (II)	TC4	L=25, L1=5	IIb	56642
030012435026	HB3.5 Headless Cannulated Screw (II)	TC4	L=26, L1=5	IIb	56642
030012435027	HB3.5 Headless Cannulated Screw (II)	TC4	L=27, L1=6	IIb	56642
030012435028	HB3.5 Headless Cannulated Screw (II)	TC4	L=28, L1=6	IIb	56642
030012435029	HB3.5 Headless Cannulated Screw (II)	TC4	L=29, L1=6	IIb	56642
030012435030	HB3.5 Headless Cannulated Screw (II)	TC4	L=30, L1=7	IIb	56642
030012435032	HB3.5 Headless Cannulated Screw (II)	TC4	L=32, L1=7	IIb	56642
030012435034	HB3.5 Headless Cannulated Screw (II)	TC4	L=34, L1=8	IIb	56642
030012435036	HB3.5 Headless Cannulated Screw (II)	TC4	L=36, L1=9	IIb	56642
030012435038	HB3.5 Headless Cannulated Screw (II)	TC4	L=38, L1=9	IIb	56642
030012435040	HB3.5 Headless Cannulated Screw (II)	TC4	L=40, L1=10	IIb	56642
030012540016	HB4.0 Headless Cannulated Screw (II)	TC4	L=16, L1=5	IIb	56642
030012540018	HB4.0 Headless Cannulated Screw (II)	TC4	L=18, L1=6	IIb	56642
030012540020	HB4.0 Headless Cannulated Screw (II)	TC4	L=20, L1=6	IIb	56642
030012540022	HB4.0 Headless Cannulated Screw (II)	TC4	L=22, L1=8	IIb	56642
030012540024	HB4.0 Headless Cannulated Screw (II)	TC4	L=24, L1=8	IIb	56642
030012540026	HB4.0 Headless Cannulated Screw (II)	TC4	L=26, L1=9	IIb	56642
030012540028	HB4.0 Headless Cannulated Screw (II)	TC4	L=28, L1=9	IIb	56642
030012540030	HB4.0 Headless Cannulated Screw (II)	TC4	L=30, L1=10	IIb	56642
030012540032	HB4.0 Headless Cannulated Screw (II)	TC4	L=32, L1=10	IIb	56642
030012540034	HB4.0 Headless Cannulated Screw (II)	TC4	L=34, L1=12	IIb	56642
030012540036	HB4.0 Headless Cannulated Screw (II)	TC4	L=36, L1=12	IIb	56642
030012540038	HB4.0 Headless Cannulated Screw (II)	TC4	L=38, L1=13	IIb	56642
030012540040	HB4.0 Headless Cannulated Screw (II)	TC4	L=40, L1=13	IIb	56642
030012540042	HB4.0 Headless Cannulated Screw (II)	TC4	L=42, L1=14	IIb	56642
030012540044	HB4.0 Headless Cannulated Screw (II)	TC4	L=44, L1=14	IIb	56642
030012540046	HB4.0 Headless Cannulated Screw (II)	TC4	L=46, L1=16	IIb	56642
030012540048	HB4.0 Headless Cannulated Screw (II)	TC4	L=48, L1=16	IIb	56642
030012540050	HB4.0 Headless Cannulated Screw (II)	TC4	L=50, L1=17	IIb	56642
030012540052	HB4.0 Headless Cannulated Screw (II)	TC4	L=52, L1=17	IIb	56642
030012540054	HB4.0 Headless Cannulated Screw (II)	TC4	L=54, L1=18	IIb	56642



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030012540056	HB4.0 Headless Cannulated Screw (II)	TC4	L=56, L1=18	IIb	56642
030012540058	HB4.0 Headless Cannulated Screw (II)	TC4	L=58, L1=20	IIb	56642
030012540060	HB4.0 Headless Cannulated Screw (II)	TC4	L=60, L1=20	IIb	56642
030012540064	HB4.0 Headless Cannulated Screw (II)	TC4	L=64, L1=22	IIb	56642
030012540068	HB4.0 Headless Cannulated Screw (II)	TC4	L=68, L1=23	IIb	56642
030012540072	HB4.0 Headless Cannulated Screw (II)	TC4	L=72, L1=24	IIb	56642
030012640020	HB4.0 Headless Cannulated Screw (II)	TC4	L=20, L2=10	IIb	56642
030012640022	HB4.0 Headless Cannulated Screw (II)	TC4	L=22, L2=11	IIb	56642
030012640024	HB4.0 Headless Cannulated Screw (II)	TC4	L=24, L2=12	IIb	56642
030012640026	HB4.0 Headless Cannulated Screw (II)	TC4	L=26, L2=13	IIb	56642
030012640028	HB4.0 Headless Cannulated Screw (II)	TC4	L=28, L2=14	IIb	56642
030012640030	HB4.0 Headless Cannulated Screw (II)	TC4	L=30, L2=15	IIb	56642
030012640032	HB4.0 Headless Cannulated Screw (II)	TC4	L=32, L2=16	IIb	56642
030012640034	HB4.0 Headless Cannulated Screw (II)	TC4	L=34, L2=17	IIb	56642
030012640036	HB4.0 Headless Cannulated Screw (II)	TC4	L=36, L2=18	IIb	56642
030012640038	HB4.0 Headless Cannulated Screw (II)	TC4	L=38, L2=19	IIb	56642
030012640040	HB4.0 Headless Cannulated Screw (II)	TC4	L=40, L2=20	IIb	56642
030012640042	HB4.0 Headless Cannulated Screw (II)	TC4	L=42, L2=21	IIb	56642
030012640044	HB4.0 Headless Cannulated Screw (II)	TC4	L=44, L2=22	IIb	56642
030012640046	HB4.0 Headless Cannulated Screw (II)	TC4	L=46, L2=23	IIb	56642
030012640048	HB4.0 Headless Cannulated Screw (II)	TC4	L=48, L2=24	IIb	56642
030012640050	HB4.0 Headless Cannulated Screw (II)	TC4	L=50, L2=25	IIb	56642
030012640052	HB4.0 Headless Cannulated Screw (II)	TC4	L=52, L2=26	IIb	56642
030012640054	HB4.0 Headless Cannulated Screw (II)	TC4	L=54, L2=27	IIb	56642
030012640056	HB4.0 Headless Cannulated Screw (II)	TC4	L=56, L2=28	IIb	56642
030012640058	HB4.0 Headless Cannulated Screw (II)	TC4	L=58, L2=29	IIb	56642
030012640060	HB4.0 Headless Cannulated Screw (II)	TC4	L=60, L2=30	IIb	56642
030012640064	HB4.0 Headless Cannulated Screw (II)	TC4	L=64, L2=32	IIb	56642
030012640068	HB4.0 Headless Cannulated Screw (II)	TC4	L=68, L2=34	IIb	56642
030012640072	HB4.0 Headless Cannulated Screw (II)	TC4	L=72, L2=36	IIb	56642
030012245025	HB4.5 Headless Cannulated Screw (II)	TC4	L=25, L0=8	IIb	56642
030012245030	HB4.5 Headless Cannulated Screw (II)	TC4	L=30, L0=8	IIb	56642
030012245035	HB4.5 Headless Cannulated Screw (II)	TC4	L=35, L0=8	IIb	56642
030012245040	HB4.5 Headless Cannulated Screw (II)	TC4	L=40, L0=12	IIb	56642
030012245045	HB4.5 Headless Cannulated Screw (II)	TC4	L=45, L0=12	IIb	56642
030012245050	HB4.5 Headless Cannulated Screw (II)	TC4	L=50, L0=12	IIb	56642
030012245055	HB4.5 Headless Cannulated Screw (II)	TC4	L=55, L0=12	IIb	56642
030012245060	HB4.5 Headless Cannulated Screw (II)	TC4	L=60, L0=12	IIb	56642
030012245065	HB4.5 Headless Cannulated Screw (II)	TC4	L=65, L0=12	IIb	56642
030012245070	HB4.5 Headless Cannulated Screw (II)	TC4	L=70, L0=12	IIb	56642
030012245075	HB4.5 Headless Cannulated Screw (II)	TC4	L=75, L0=16	IIb	56642
030012245080	HB4.5 Headless Cannulated Screw (II)	TC4	L=80, L0=16	IIb	56642
030012245085	HB4.5 Headless Cannulated Screw (II)	TC4	L=85, L0=16	IIb	56642



