



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System No. 21 0189 QS/NB

The quality system of manufacturer

MEDIN, a.s.

Vlachovická 619, Nové Město na Moravě 592 31, Czech Republic

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Orthopaedic bone screws (non-absorbable, non-sterile), Femur Nails (non-sterile)

The Notified Body No. 1023 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 subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2021-05-11

Valid until: 2024-05-27

First Issued: 2021-05-11

Revision: -

Date: 2021-05-11



Mgr. Jiří Heš

Representative of the Notified Body No. 1023



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Annex to EC Certificate No. 21 0189 QS/NB

issued for manufacturer:

MEDIN, a.s.
Vlachovická 619, Nové Město na Moravě 592 31, Czech Republic


Product(s):

Name: Cannulated headless screw Ti
Trade name(s): Cannulated headless screw Ti
Model(s): see table
Class: IIb
GMDN: 56642

Article number	Variant
397 129 70 6804	self-tapping; 2,5×14/5 mm
397 129 70 6814	self-tapping; 2,5×16/5 mm
397 129 70 6824	self-tapping; 2,5×18/5 mm
397 129 70 6834	self-tapping; 2,5×20/5 mm
397 129 70 6844	self-tapping; 2,5×22/6 mm
397 129 70 6854	self-tapping; 2,5×24/6 mm
397 129 70 6864	self-tapping; 2,5×26/6 mm
397 129 70 6874	self-tapping; 2,5×28/6 mm
397 129 70	self-tapping; 2,5×30/6 mm

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Article number	Variant
6884	
397 129 71 2204	self-tapping; 2,5×20/8 mm
397 129 71 2214	self-tapping; 2,5×22/8 mm
397 129 71 2224	self-tapping; 2,5×24/9 mm
397 129 71 2234	self-tapping; 2,5×26/9 mm
397 129 71 2244	self-tapping; 2,5×28/10 mm
397 129 71 2254	self-tapping; 2,5×30/10 mm
397 129 70 7574	self-tapping; 3×12/5 mm
397 129 70 7584	self-tapping; 3×14/5 mm
397 129 70 7594	self-tapping; 3×16/5 mm
397 129 70 7604	self-tapping; 3×18/5 mm
397 129 70 7614	self-tapping; 3×20/5 mm
397 129 70 7624	self-tapping; 3×22/6 mm
397 129 70 7634	self-tapping; 3×24/6 mm



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Article number	Variant
397 129 70 7644	self-tapping; 3×26/6 mm
397 129 70 7654	self-tapping; 3×28/6 mm
397 129 70 7664	self-tapping; 3×30/6 mm
397 129 71 1554	self-tapping; 3×16/7 mm
397 129 71 1564	self-tapping; 3×18/7 mm
397 129 71 1574	self-tapping; 3×20/8 mm
397 129 71 1584	self-tapping; 3×22/8 mm
397 129 71 1594	self-tapping; 3×24/9 mm
397 129 71 1604	self-tapping; 3×26/10 mm
397 129 71 1614	self-tapping; 3×28/10 mm
397 129 71 1624	self-tapping; 3×30/12 mm
397 129 71 1634	self-tapping; 3×32/12 mm
397 129 70 7704	self-tapping; 4×26/7 mm
397 129 70 7714	self-tapping; 4×28/7 mm



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Article number	Variant
397 129 70 7724	self-tapping; 4×30/7 mm
397 129 70 7734	self-tapping; 4×32/7 mm
397 129 70 7744	self-tapping; 4×34/7 mm
397 129 70 7754	self-tapping; 4×36/7 mm
397 129 70 7764	self-tapping; 4×38/7 mm
397 129 70 7774	self-tapping; 4×40/8 mm
397 129 70 7784	self-tapping; 4×45/9 mm
397 129 70 7794	self-tapping; 4×50/10 mm
397 129 70 7804	self-tapping; 4×55/11 mm
397 129 70 7814	self-tapping; 4×60/12 mm
397 129 71 2284	self-tapping; 4×30/12 mm
397 129 71 2294	self-tapping; 4×32/12 mm
397 129 71 2304	self-tapping; 4×34/13 mm
397 129 71 2314	self-tapping; 4×36/14 mm

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Article number	Variant
397 129 71 2324	self-tapping; 4×38/15 mm
397 129 71 2334	self-tapping; 4×40/16 mm
397 129 71 2344	self-tapping; 4×45/18 mm
397 129 71 2354	self-tapping; 4×50/20 mm
397 129 71 2364	self-tapping; 4×55/22 mm
397 129 71 2374	self-tapping; 4×60/24 mm

Name: Reconstruction nail PLATON Ti
Trade name(s): Reconstruction nail PLATON Ti
Model(s): see table
Class: IIb
GMDN: 56643

Ref.no.	Variant
Reconstruction nail PLATON Ti	
110 - 407	L, 10x280 mm, 125°, right
110 -	L, 10x300 mm, 125°,



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Ref.no.	Variant
408	right
110 - 409	L, 10x320 mm, 125°, right
110 - 410	L, 10x340 mm, 125°, right
110 - 411	L, 10x360 mm, 125°, right
110 - 412	L, 10x380 mm, 125°, right
110 - 413	L, 10x400 mm, 125°, right
110 - 414	L, 10x420 mm, 125°, right
110 - 417	L, 10x280 mm, 130°, right
110 - 418	L, 10x300 mm, 130°, right
110 - 419	L, 10x320 mm, 130°, right
110 - 420	L, 10x340 mm, 130°, right
110 - 421	L, 10x360 mm, 130°, right
110 - 422	L, 10x380 mm, 130°, right
110 - 423	L, 10x400 mm, 130°, right

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issued for manufacturer:

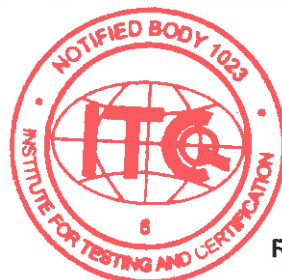
MEDIN, a.s.

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Ref.no.	Variant
110 - 424	L, 10x420 mm, 130°, right
110 - 427	L, 10x280 mm, 125°, left
110 - 428	L, 10x300 mm, 125°, left
110 - 429	L, 10x320 mm, 125°, left
110 - 430	L, 10x340 mm, 125°, left
110 - 431	L, 10x360 mm, 125°, left
110 - 432	L, 10x380 mm, 125°, left
110 - 433	L, 10x400 mm, 125°, left
110 - 434	L, 10x420 mm, 125°, left
110 - 437	L, 10x280 mm, 130°, left
110 - 438	L, 10x300 mm, 130°, left
110 - 439	L, 10x320 mm, 130°, left
110 - 440	L, 10x340 mm, 130°, left
110 -	L, 10x360 mm, 130°, left

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Ref.no.	Variant
441	
110 442	- L, 10x380 mm, 130°, left
110 443	- L, 10x400 mm, 130°, left
110 444	- L, 10x420 mm, 130°, left
110 400	- S, 10x190 mm, 125°
110 401	- S, 10x190 mm, 130°
Locking screw PLATON Ti	
101 140	- 5x25 mm
101 141	- 5x30 mm
101 142	- 5x35 mm
101 143	- 5x40 mm
101 144	- 5x45 mm
101 145	- 5x50 mm
101 146	- 5x55 mm

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Ref.no.	Variant
101 - 147	5x60 mm
101 - 148	5x65 mm
101 - 149	5x70 mm
101 - 150	5x75 mm
101 - 151	5x80 mm
101 - 152	5x85 mm
101 - 153	5x90 mm
101 - 154	5x95 mm
Femoral Lag screw PLATON Ti	
110 - 198	12x75 mm
110 - 199	12x80 mm
110 - 200	12x85 mm
110 - 201	12x90 mm
110 -	12x95 mm

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Ref.no.	Variant
202	
110 203	- 12x100 mm
110 204	- 12x105 mm
110 205	- 12x110 mm
110 206	- 12x115 mm
110 207	- 12x120 mm
End cap PLATON Ti	
110 301	- M12, L15
Set screw PLATON Ti	
110 308	- M8, L27 mm
110 309	- for AR Clip, M8, L22 mm

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Ref.no.	Variant
Connection screw PLATON Ti	
110 - 304	M7, L20
AR-Clip PLATON TI	
110 - 299	XS
110 - 303	S
110 - 305	M
110 - 307	L
110 - 311	XL


Facility(ies):

MEDIN, a.s.

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Certificate History:

Revision	Date	Reference Number	Action
	2021-05-11	803602899	Certification



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