

EC CERTIFICATE**Annex II excluding section 4 of the Directive 93/42/EEC on Medical Devices****Full Quality Assurance System****Certificate Number****CE-MDD-0085/07/2020/01**

Manufacturer : TiNiKo Co., Ltd.

Address : 204, 48, Jungsimsangeop 2-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea.

Product(s) : -Metallic Spinal Bone Fixator (Brand Name: SPINElant)
-Metallic Bone Trauma Fixator (Brand Name: BONEIant)

Model(s) : Please see 2nd page for details of products.

Report Number : CE-MED-0085-01
CE-MED-0085-02

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Revision Number and Date : 00 / --

Validity Date : 2024.05.26

NOTICE, Notified Body 2764, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits. NOTICE must be informed of any significant changes in the design and/or construction of the product(s).

Özlem Vicdan Akdağ
Chairman



**NOTİCE BELGELENDİRME
MUAYENE VE DENETİM
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Esentepe Mahallesi Milangaz Caddesi
No:75/A/92 Kartal / İstanbul / TÜRKİYE
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Product Name	Model Type	Model Name
METALLIC SPINAL BONE FIXATOR	Normal Type	- SPINElant CESL 1621 - SPINElant CESL 1826 - SPINElant CESL 1831 - SPINElant CESL 2036 - SPINElant CESL 2240
	One Round Type	- SPINElant LBSL 2924 - SPINElant LBSL 2929 - SPINElant LBSL 2934 - SPINElant LBSL 2939 - SPINElant LBSL 2944 - SPINElant LBSL 2949 - SPINElant LBSL 2954
	Two Round Type	- SPINElant LBSL 2959 - SPINElant LBSL 2964 - SPINElant LBSL 2969
	Three Round Type	- SPINElant LBSL 2974 - SPINElant LBSL 2979 - SPINElant LBSL 2984 - SPINElant LBSL 3289 - SPINElant LBSL 3294 - SPINElant LBSL 3299

Product Name	Model Type	Sub Model Type
METALLIC BONE TRAUMA FIXATOR	Round Type	- Double-ring - Single-ring
	G-Shaped Type	- Double-ring - Single-ring
	D-Shaped Type	- Double-ring - Single-ring
	O-Flattened Type	- Double-ring - Single-ring
	Delte-Shaped Type	- Double-ring - Single-ring
	Ellipse-Shaped Type	- Double-ring - Single-ring
	Complicated Fractures Type	---
	Commiuted Wedge Fractures Type	---
	Coracoclavicular Fractures Type	---



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