EC Declaration of Conformity

Manufacturer:
Jiangsu Jinlu Group Medical Device Co., Ltd
Jinfeng Town,Zhangjiagang City Jiangsu Province,China

whose single Authorized Representative:
Prolinx GmbH
Brehmstr. 56, 40239, Duesseldorf

We, the manufacturer, herewith declare that the products

Bone-screw internal spinal fixation system, non-sterile

(including system components and accessories)
UMDNS-Code: **61325**; *GMDN-Code:* **61325**

meet the provisions of Directive 93/42/EEC (amended by 2007/47/EC) which apply to them.

The medical device has been assigned to class **IIb** according to Annex IX of the Directive 93/42/EEC(amended by 2007/47/EC). It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex **IIb** of Directive 93/42/EEC (amended by 2007/47/EC).

Compliance of the designated product with the Directive 93/42/EEC (amended by 2007/47/EC) has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Am Grauen Stein D-51105 Köln
Certificate No.: 15096167001
Issue date: 2017-12-11
Expiry date:2022-06-30
following the procedure relating to the EC Declaration of Conformity set out in Annex **IIb** of Directive 93/42/EEC (amended by 2007/47/EC).

The above mentioned declaration of conformity is exclusively under the responsibility of:

Jiangsu Jinlu Group Medical Device Co., Ltd

Zhangjiagang April 15 2019
Place, date

JIANPING Xu Manager
Legally binding signature, Function

Şavga Nicolae

Подписано цифровой подписью: Şavga Nicolae
DN: cn=Şavga Nicolae, serialNumber=0980502027463, l=or. Chisinau, st=Republica Moldova, 2.5.4.20=79755402, street=SEC.RISCANI STR.MOSCOVA BD. 20/2 AP.20, postalCode=2000, c=MD, o
Дата: 2019.04.16 06:43:25 +03'00'