

# EC CONFORMITY DECLARATION

Number PSEN0021

Version 02

Date and place of issue: 30. 11. 2015, Želevčice

**Conformity declaration issued by:**

Commercial name	Linet spol. s r. o.
Registered address	Želevčice 5, 274 01 Slaný, Czech Republic
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As the producer of the product - name (brand):

**Praktika**

Variants of the product:

**Praktika 1, Praktika 2****1F1, 1F2**

(Variants are specified in the technical documentation of the product).

Description and function designation:

Manually adjustable hospital bed intended for standard and long term care.

This EC conformity declaration also covers all applicable accessories approved by manufacturer.

Classification of the product as the medical device:

**Class I** nonsterile, without measuring function, according to annex IX MDD 93/42/EEC – rule 1**A) Declaration**

I declare that the said product is safe under the conditions of common use in compliance with the instructions and that measures have been taken to ensure the conformity of all the products brought to market with basic requirements of directives related thereto, stated in paragraph B.

**B) Fulfilled technical requirements of related regulations**

This product's characteristics comply with the technical parameters related to it and stated in MDD 93/42/EEC which stipulates the technical parameters for healthcare products, with applicable specific requirements in directive 2006/42/EC which stipulates the technical parameters for machinery devices.

**C) Means of assessing conformity**

Conformity was assessed by the procedure stated MDD 93/42/EEC, Annex VII.

**D) Used standards for product conformity assessment**

The said product fulfills the requirements of these harmonized technical standards which were used for assessing of conformity: EN 60601-1:2006/A1:2013, EN60601-2-52:2010, EN ISO 14971:2012, EN ISO 10993-5:2009 and EN ISO 10993-10:2013.

  
Ing. Tomáš Kolář  
managing director