

# EC CONFORMITY DECLARATION

Number PSEN0022

Version 01

Date and place of issue: 09. 07. 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):

**EffectaCare, CliniCare, PrimaCare**

Variants of the product:

<b>EffectaCare 10</b>	<b>CliniCare 10</b>	<b>PrimaCare 10</b>
<b>EffectaCare 20</b>	<b>CliniCare 20</b>	<b>PrimaCare 20</b>
	<b>CliniCare 30</b>	

**4PP**

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

Description and function designation:

Passive preventive antidecubitus mattress for medical, nursing and home care.

This EC conformity declaration also covers all applicable accessories.

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.

**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: ISO 10993-5:2009, ISO 10993-10:2010 and non-harmonized technical standards: BS 7175:1989. which were used for assessing of conformity

Ing. Tomáš Kolář  
managing director