

EC CONFORMITY DECLARATION

Date of issue: 21. 3. 2010

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):	Ergomatt
Variants of the product:	Variants are specified in the technical documentation of the product.
Description and function designation:	Preventive antidecubitus mattress intended for use in the standard and/or intensive hospital care.
Classification of the product as the medical device:	Class I nonsterile, without measuring function

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

This product's characteristics comply with the technical parameters related to it and stated in MDD 93/42/EEC as amended, 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

The said product fulfils the requirements of these harmonized technical standards which were used for assessing of conformity: EN ISO 10993-5:1999, BS EN ISO 10993-10, EN ISO 14971:2007.



Ing. Zbyněk Frolík
managing director