EC CONFORMITY DECLARATION

Date of issue: 16.3.2012

Conformity declaration issued by:	
Commercial name	**Linet spol. s r. o.**
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As the producer of the product - name (brand):	**Latera**
Variants of the product:	**1L** (Variants are specified in the technical documentation of the product).
Description and function designation:	Electrically operated hospital bed intended for use in the standard care, acute care and/or long-term care, including all applicable accessories.
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, in directive 2004/108/ES as amended which stipulates the technical parameters of products concerning their electromagnetic compatibility and directive 2006/42EC as amended which stipulates the technical parameters for machinery device.

C) Means of assessing conformity

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

D) Used standards

The said product fulfills the requirements of these harmonized technical standards which were used for assessing of conformity: EN60601-1:2006, EN 60601-1-2:2007, EN 60601-1-6:2010, EN 60601-2-52:2010.

Ing. Zbyněk Frolík
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