EC CONFORMITY DECLARATION

Date and place of issue: 12.05.2015, Želevčice

Conformity declaration issued by:	
Commercial name	**Linet spol. s r. o.**
Registered address	Želevčice 5, 274 01 Slaný, Czech Republic
Reg. No.	00507814
Telephone	+420 312 576 111
Fax	+420 312 522 668

As the producer of the product - name (brand):	**Latera**
Variants of the product:	**Latera Acute, Latera Thema** **1L** (Variants are specified in the technical documentation of the product).
Description and function designation:	Electrically operated hospital bed, intended for use in standard, acute and long term 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 12

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 and with requirements in directive 2011/65/EU which stipulates the restriction of the use of certain hazardous substances in electrical and electronic equipment.

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, EN 60601-1-2:2007, EN 60601-1-6:2010, EN60601-2-52:2010 and EN ISO 14971:2012.

Ing. Tomáš Kolář
managing director

CE

Linet spol. s r.o., Želevčice 5, 274 01 Slaný, Czech Republic
tel.: +420 312 576 111, fax: +420 312 522 668, e-mail: info@linet.cz, web: www.linet.cz