EC DECLARATION OF CONFORMITY

Number:	PSEN0012
Version:	02

1. Product - instrument Type / Model:

Electrically operated hospital bed – ***Latera / 1L***

2. Name and address of the manufacturer:

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

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of declaration:

Product:	**Latera Acute, Latera Thema**
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 approved by manufacturer.
Classification of the product as the medical device:	**Class I** non sterile, without measuring function, according to annex IX of Government Order No.54/2015 Coll. (MDD 93/42/EEC) – rule 12

5. The object of the declaration described above is in conformity with the relevant Union harmonization legislation:

- Act No. 268/2014 Coll., on Medical Devices (Directive 93/42/EEC)
- Act No. 350/2011 Coll., on chemical substances and mixtures (Regulation (EC) No 1907/2006)
- Government Order No.54/2015 Coll., with is specifies technical requirements for medical devices (Directive 93/42/EEC)
- Government Order No.481/2012 Coll., on the restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)

6. References to the relevant harmonized standards used or references to the other technical specifications in relation to which conformity is declared:

EN 60601-1:2006/A1:2013, EN 60601-1-2:2007, EN 60601-1-6:2010, EN 60601-2-52:2010, EN ISO 14971:2012

Place and date of declaration issue: Slaný, 20.07.2018

Signed for and on behalf of **LINET spol. s r.o.**

Ing. Tomáš Kolář, Managing Director

CE