

EC DECLARATION OF CONFORMITY

Number:

PSEN0030

Version:

02



1. Product - instrument Type / Model:

Electrically operated hospital bed with scales – *Eleganza 5 / 1GE5*

2. Name and address of the manufacturer:

Commercial name	LINET spol. s r.o.
Registered address	Železčice 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:	Eleganza 5 with scales (WS17)
Description and function designation:	Electrically operated hospital bed with scales, intended for use in intensive and acute care. This EC conformity declaration also covers all applicable accessories.
Classification of the product as the medical device:	Class I non sterile, with 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)
- Applicable requirements of Government Order No.176/2008 Coll., on machinery devices (Directive 2006/42/EC)
- 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)
- Government Order No.121/2016 Coll., on non-automatic weighing instruments (Directive 2014/31/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 60601-1-2:2015, EN 60601-1-6:2010, EN 60601-2-52:2010, EN ISO 14971:2012, EN 45501:2015, EN ISO 10993-5:2009 and EN ISO 10993-10:2013.

7. Notified body

Name and number of NB	Performed	Issue the Certificate No.
Czech Metrology Institute, NB 1383 Okružní 31, 638 00 Brno, Czech Republic	EU type examination in accordance with Module B of Government Order No.121/2016 Coll. (module B of Directive No. 2014/31/EU)	TCM 128/17-5444
Czech Metrology Institute, NB 1383 Okružní 31, 638 00 Brno Czech Republic	Certification / approval of Quality Management System for production and testing of non-automatic weighing instruments in accordance with Annex II, module D of Government Order No.121/2016 Coll. (Annex II, module D of Directive No. 2014/31/EU)	0115-SJ-C002-06
Electrotechnical testing institute, NB 1014, Pod Lisem 129/2, 171 02 Praha 8-Troja- Praha 8, Czech Republic	Conformity assessment in accordance with Annex II and VII of Government Order No.54/2015 Coll. (Annex II and VII of Directive 93/42/EEC)	MED 170016

8. Another information

We hereby declare that the above mentioned energy meters are fulfill in Directive 2014/32/EU of the European Parliament and the Council.

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