

EU DECLARATION OF CONFORMITY	Number:	DOCENEleganza4m
	Version:	01
	Validity until:	07.03.2027

1. Product - instrument Type/Model:

Electrically operated hospital bed with scales – *Eleganza 4 / 1GE4*

2. Name and address of the manufacturer:

Commercial name	L I N E T spol. s r.o.
Registered address	Želevčice 5, 274 01 Slaný, Czech Republic
Single registration number (SRN)	CZ-MF-000009320

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

Product:	Eleganza 4 with scales (WS17)
Description and function designation:	Electrically operated hospital bed with scales, intended for use in acute and intensive care. This EU conformity declaration also covers all applicable accessories approved by manufacturer.
Basic UDI-DI	8592654348701CK
Classification of the product as the medical device:	Class I , non sterile, with measuring function, according to Rule 13, annex VIII to Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR)

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

- Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (MDR)
- 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/A1:2015, EN 60601-2-52:2010/A1:2015, EN ISO 14971:2019, 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
TÜV SÜD Product Service GmbH Zertifizierstellen, NB 0123 Ridlerstraße 65 80339 München Germany	Conformity assessment in accordance with annex IX, chapters I and III to Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR)	G11 067069 0039 Rev. 00

Place and date of declaration issue: Slaný, 9.3.2022

Signed for and on behalf of L I N E T spol. s r.o.

Ing. Tomáš Kolář, Managing Director