

<b>EU DECLARATION OF CONFORMITY</b>	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	Želečnice 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:	<b>Eleganza 4 with scales (WS17)</b>
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	<b>8592654348701CK</b>
Classification of the product as the medical device:	<b>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)</b>

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

<ul style="list-style-type: none"> <li>- Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (MDR)</li> <li>- Applicable requirements of Government Order No.176/2008 Coll., on machinery devices (Directive 2006/42/EC)</li> <li>- 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)</li> <li>- Government Order No.121/2016 Coll., on non-automatic weighing instruments (Directive 2014/31/EU)</li> </ul>
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**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
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**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.

  
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 Ing. Tomáš Kolář, Managing Director