

<b>UK DECLARATION OF CONFORMITY</b>	Number:	UKDOCEleganza1
	Version:	01

**1. Product - instrument Type / Model:**

Electrically operated hospital bed – *Eleganza 1 / 1GT*

**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

**3. Name and address of the UK responsible person:**

Commercial name	LINET UK Ltd,
Registered address	11 Brunel Way, Segensworth East, Fareham, Hampshire, PO15 5TX, United Kingdom

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

**5. Object of declaration:**

Product:	<b>Eleganza 1</b>
Description and function designation:	Electrically operated hospital bed intended for use in standard and acute care. This UK conformity declaration also covers all applicable accessories approved by manufacturer.
Basic UDI-DI	<b>8592654348700CH</b>
Classification of the product as the medical device:	<b>Class I non sterile, without measuring function, rule 12, according to Medical Device Regulation 2002 (SI 618)</b>

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

- Medical Device Regulation 2002 (SI 618) as amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478)
- Applicable requirements of Directive 2006/42/EC on machinery devices
- UK REACH - REACH etc. (Amendment) Regulations 2021
- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
- UK RoHS regulations 2012, UK Statutory instrument 2012 no 3032
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

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

BS EN 60601-1:2006/A2:2021, BS EN 60601-1-2:2015/A1:2021, BS EN 60601-1-6:2010/A2:2021, **BS EN 60601-2-52:2010 /A1:2015**, BS EN ISO 10993-5:2009, BS EN ISO 10993-10:2021, BS EN ISO 14971:2019 /A11:2021, BS EN ISO 15223-1:2021

Place and date of declaration issue: Slaný, 2.1.2023

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

  
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 Ing. Tomáš Kolář, Managing Director

