

UK DECLARATION OF CONFORMITY	Number:	UKDOCEleganza2
	Version:	01

1. Product - instrument Type / Model:

Electrically operated hospital bed – *Eleganza 2 / 1GR*

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:	Eleganza 2
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	8592654348700CH
Classification of the product as the medical device:	Class I non sterile, without measuring function, rule 12, according to Medical Device Regulation 2002 (SI 618)

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, 16.1.2023

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



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Ing. Tomáš Kolář, Managing Director

