



# Certificate

No. Q5 067069 0038 Rev. 02

Holder of Certificate:

**LINET**

**L I N E T spol. s r.o.**

Želevčice 5  
274 01 Slaný  
CZECH REPUBLIC

Certification Mark:



Scope of Certificate:

**Design and development, manufacture, distribution, servicing and installation of hospital beds, nursing beds, birthing beds, ICT solutions, stretchers, anti-decubitus systems and mattresses and furniture for the areas of hospital care, gynaecology, social care and home care**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:Q5 067069 0038 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 067069 0038 Rev. 02)

Report No.:

713204634

Valid from:

2022-06-16

Valid until:

2024-07-22

Date,

2022-06-16

Christoph Dicks  
Head of Certification/Notified Body

# Certificate

No. Q5 067069 0038 Rev. 02

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** **L I N E T spol. s r.o.**  
Želevčice 5, 274 01 Slaný, CZECH REPUBLIC

Design and development, manufacture, distribution, servicing and  
installation of hospital beds, nursing beds, birthing beds, ICT  
solutions, stretchers, anti-decubitus systems and mattresses and  
furniture for the areas of hospital care, gynaecology, social care  
and home care

**L I N E T spol. s r.o.**  
Politických vězňů 1969, 274 01 Slaný, CZECH REPUBLIC

Manufacturing of hospital beds and nursing beds for the areas of  
hospital care, gynaecology, social care and home care

<b>DECLARAȚIA DE CONFORMITATE UE</b>	Număr:	DOCROEleganza1
	Versiune:	02

**1. Tip/Model de produs - instrument:**

Pat de spital acționat electric – **Eleganza 1 / 1GT**

**2. Numele și adresa producătorului:**

Nume comercial	<b>L I N E T spol. s r.o.</b>
Sediu social	Želevčice 5, 274 01 Slaný, Republica Cehă
Număr unic de înregistrare (SRN)	CZ-MF-000009320

**3. Această declarație de conformitate este emisă sub răspunderea exclusivă a producătorului.**
**4. Obiectul declarației:**

Produsul:	<b>Eleganza 1</b>
Descriere și clasificare funcțională:	Pat de spital acționat electric, destinat utilizării în secțiile standard de urgențe. Această declarație de conformitate UE acoperă, de asemenea, toate accesoriile aplicabile.
Identificatorul unic de bază al dispozitivului, UDI-DI-ul de bază	<b>8592654348700CH</b>
Clasificarea produsului ca dispozitiv medical:	<b>Clasa I</b> nesteril, fără funcție de măsurare, conform Anexei VIII a Regulamentului (UE) 2017/745 al Parlamentului European și al Consiliului (MDR) - Regula 13

**5. Obiectul declarației descris mai sus este în conformitate cu legislația de armonizare relevantă a Uniunii:**

<ul style="list-style-type: none"> <li>- Regulamentul (UE) 2017/745 al Parlamentului European și al Consiliului (MDR)</li> <li>- Legea nr. 350/2011 Coll. privind substanțele și amestecurile de substanțe chimice (Regulamentul [CE] nr. 1907/2006)</li> <li>- Cerințele aplicabile ale Hotărârii de Guvern nr. 176/2008 Coll. privind dispozitivele și utilajele (Directiva 2006/42/CE)</li> <li>- Hotărârea de Guvern nr. 481/2012 Coll privind restricțiile de utilizare a anumitor substanțe periculoase în echipamentele electrice și electronice (Directiva 2011/65/UE)</li> </ul>
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**6. Referințe la standardele armonizate aplicabile utilizate sau la alte specificații tehnice pe baza cărora este declarată conformitatea:**

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 ISO 10993-5:2009, EN ISO 10993-10:2013
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Locul și data emiterii declarației: Slaný, 23.7.2021

Semnat în numele L I N E T spol. s r.o.



.....  
Ing. Tomáš Kolář, Director general



# Eleganza 1



excellent solution for economical reasons

# Eleganza 1





- Ergoframe® reduces the pressure load
- Easy mobilisation
- Available with a number of controls



Patient

- Soft drop function of siderails
- Easy clean concept
- Safety features such as the Extender or Protector



Staff

- Low TCO – total cost of ownership
- Universal bed for a low price
- Overload protection



Management



# Improved patient care

## COMFORT FOR EVERYONE

The bed accommodates hospitalised overweight or taller patients.

- Robust construction.
- Safe working load 180–250 kg.
- Mattress platform width 90 cm.
- Possible bed extension by 15 cm.
- Split plastic siderails with soft drop function.



## CONTROLS WITHIN REACH

Several clear and easy to use controls are immediately at the patient's disposal.

- 1 Handset**  
to control the bed positions can also come with a back lit keyboard.
- 2 Satellite control panel**  
comes on a flexible arm and is easy to access, the buttons are embossed for vision impaired patients.
- 3 Controls in the siderails**  
are easy to use and always to hand.





THE ERGOFRAME<sup>®</sup> system extends the mattress platform in the pelvic area and reduces the pressure load on the tissues in this region when a patient is positioned in the cardiac chair position.



## EASIER MOBILISATION

The mattress platform is equipped with an integrated holder for the which assisted helps with patient mobilisation.





# Safety first

## SAFE SIDERAILS

The bed can be equipped with soft drop function of split plastic siderails. The safety of the split plastic siderails is guaranteed by a system of two independent unlocking movements.

- The single  $\frac{3}{4}$  siderail controls are located ergonomically for the first time at the top of the siderail.
- The siderails are lowered using the soft drop function which applies a gas spring to soften the effect of the siderail's movement.



## THE UNIQUE PROTECTOR

The use of the Protector enables protection along the entire length of the mattress platform. The Protector is located at the foot end of the bed and is linked to the single collapsible siderail both in terms of dimensions and design.





## BETTER PROTECTION

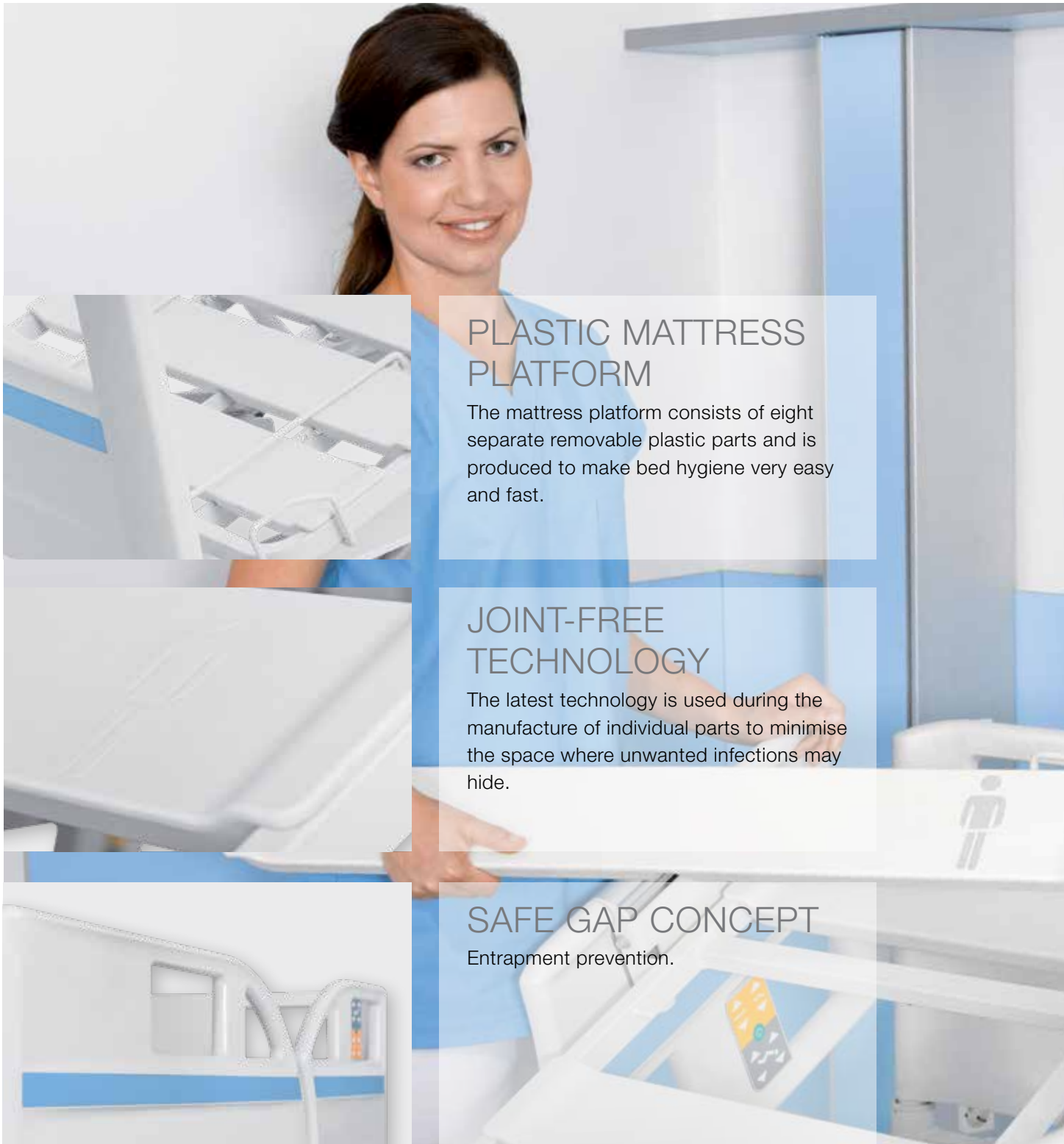
In some cases it is appropriate to provide the patient with a higher level of protection. An easy-to-assemble extension piece makes the siderail 10 cm higher. The Extender is especially recommended when using an active mattress – up to 26.5 cm height.

## GO BUTTON

The green GO button activate the bed control units for a period of 3 minutes from when last pushed.



# Easy clean concept



## PLASTIC MATTRESS PLATFORM

The mattress platform consists of eight separate removable plastic parts and is produced to make bed hygiene very easy and fast.

## JOINT-FREE TECHNOLOGY

The latest technology is used during the manufacture of individual parts to minimise the space where unwanted infections may hide.

## SAFE GAP CONCEPT

Entrapment prevention.

# Staff friendly



## 5<sup>th</sup> CASTOR

The activated 5<sup>th</sup> castor makes transfer through long corridors easier. Creating a turning point in the middle of the bed, it allows for tight turns, also providing significant reduction in the force needed to turn the bed.



## SUPERVISOR CONTROL PANEL

The panel has a coiled cable providing flexibility of movement and operation of the bed from an optimum position.



## CENTRAL CONTROL PANEL

The panel for the control and deactivation of the functions is located under the foot end and is integrated into the bed frame.



## FOOT CONTROLS

The controls allow the practical and easy adjustment of the height and examination position. They are equipped with a mechanical protector against accidental activation.



# Eleganza 1 Extra SAFE

## SAFE ZONE FOR PATIENTS

The Eleganza 1 Extra SAFE offers a high quality standard of hospital bed. Thanks to the modifications it is suitable for specific departments such as psychiatric, prison hospital, mental health etc.



1

The Ergoframe® system extends the mattress platform in the pelvic area and reduces the pressure load on the tissues in this region when a patient is positioned in the cardiac chair position.

2

Cardiac chair  
The position can be set by pressing a single button.

### Basic equipment of Eleganza 1 Extra SAFE \*

Fixed mattress platform covers	Plug and Play connector of the patient's handset
Fixed tube ends	Back-up battery
Fixed end decors	Supervisory panel with cardiac chair functions, TR and ATR by pressing a single button
Built-in supervisory panel in the line shelf	Protection of the supply cable in a locking box

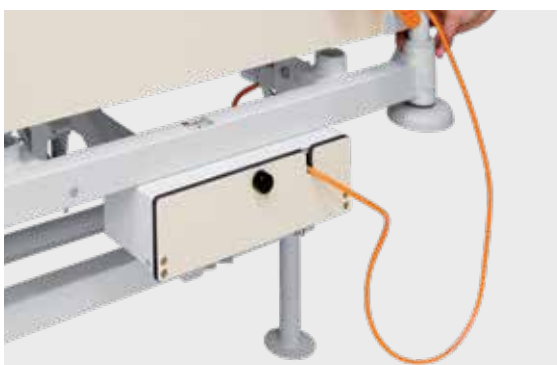
\* Unlike the standard Eleganza 1 version





## FIXED PARTS

The entire bed and its panels are firmly installed and the mattress platform parts are also fixed. All smaller parts of the bed, such as the hooks on the accessory bar, are secured.



## CABLE PROTECTION

The power supply cable is hidden in a lockable box with easy and practice key (Segufix key).



## SEGUFIX KEY

The Segufix is compatible, and the operator does not need any additional keys.



## FIXED VERSION

A bed in a version without castors can be fixed to the floor.

# Eleganza 1 LE

## COST-EFFECTIVE VERSION

The Eleganza 1 LE bed construction is the same as the classic Eleganza 1 model: lift, maximum load, undercarriage including all versions of castors and brakes, mattress platform and ends. It also comes with either single collapsible siderails or split plastic siderails.

The bed's control unit is simpler.





The simplified version of the Eleganza 1 LE bed offers high functionality at a more affordable price.

- Universal control box 100–240 V.
- Bed can be equipped with a Plug and Play handset.
- 1 lever of mechanical CPR (possible upgrade for standard 2 levers).



## BED CONTROL

The Eleganza 1 LE is equipped with a simpler control unit, so the bed can be controlled by a single handset. A simple handset controls the electrical positioning and height setting.

- With mechanical lock.
- 8 or 10 buttons (two buttons for tilting into the TR/ATR position).



A more affordable version of the non-tilting electric bed.

# Practical details

1

## Removable bed ends

can be fixed to the mattress platform frame with simple eccentric locks.

2

## Horizontal corner bumpers

protect the bed.

3

## Mattress platform

is easily removable and cleanable and is compatible with 86 or 90 cm mattresses.

4

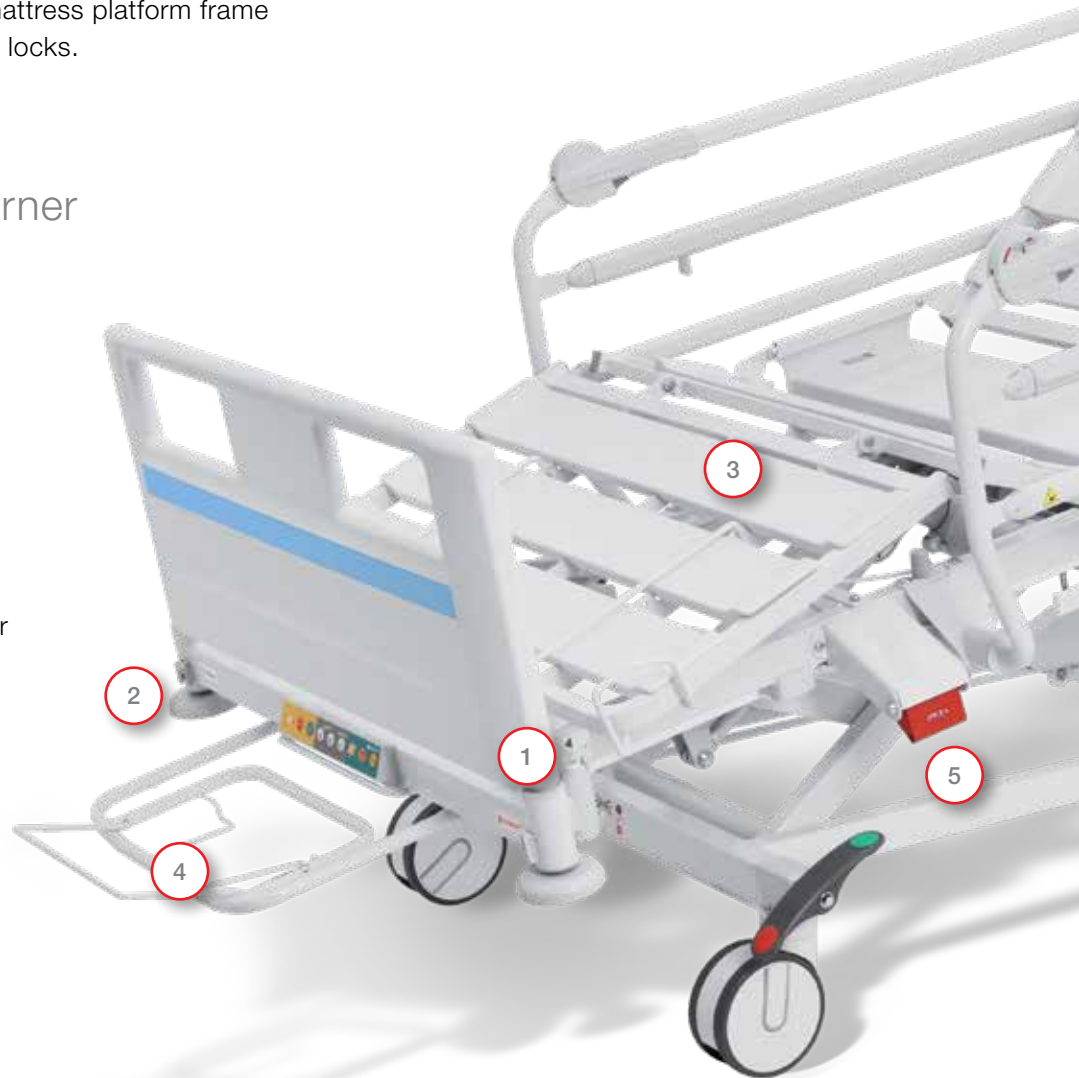
## Linen shelf

may also be used to store the supervisor panel.

5

## Mechanical CPR

– additional option for electrical CPR urgent use





## COLOUR OPTIONS

The practical, modest and very attractive design of the Eleganza 1 bed together with a wide range of colour effects creates a pleasant and up-to-date hospital environment.



### Safe working load

Castors		Battery	
Dimensions	Braking	Without battery	With battery
125 mm	Individually braked	185 kg	
	Centrally braked	200 kg	250 kg
150 mm	Centrally braked		

### Technical parameters

	Castors	
	125 mm	150 mm
External dimension	218 × 99 cm	
Bed extension	15 cm	
Mattress platform	4 section, electric adjustable	
Mattress platform dimensions	200 × 90 × 14 cm	
Electric height adjustment	37 – 73.5 cm	39.5 – 76 cm
Electric backrest adjustment	0 – 70°	
Electric thighrest adjustment	0 – 35°	
TR / ATR	15° – 15°	
Ergoframe®	9 + 7 cm	
Bed weight (as specified)	135 kg	
Standard	IEC: 60601-2-52	
Protection against water and dust	IPx4	
Overload protection	Yes	
Clearance for server	16 cm	18.8 cm





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**LINET**

Members of LINET Group

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