# EC DECLARATION OF CONFORMITY

| Number: | PSEN0026 |
|---|---|
| Version: | 04 |

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

Reactive mattress – ***CliniCare 100 HF / 3VC0, 1VCK, 4VCM***

**2. Name and address of the manufacturer:**

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|---|---|
| Commercial name | **LINET spol. s r.o.** |
| Registered address | Želevčice 5, 274 01 Slaný, Czech Republic |
| Reg. No. | 00507814 |
| Telephone | +420 312 576 111 |
| Fax | +420 312 522 668 |

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

**4. Object of declaration:**

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|---|---|
| Product: | **CliniCare 100 HF** |
| Description and function designation: | Reactive mattress - hybrid of passive mattress and active mattress with blower. The mattress for the patients in all risk of pressure ulcers development.<br>This EC conformity declaration also covers all applicable accessories. |
| Classification of the product as the medical device: | **Class I** non sterile, without measuring function, according to annex IX of Government Order No.54/2015 Coll. (MDD 93/42/EEC) – rule 12 |

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

- Act No. 268/2014 Coll., on Medical Devices (Directive 93/42/EEC)
- Act No. 350/2011 Coll., on chemical substances and mixtures (Regulation (EC) No 1907/2006)
- Government Order No.54/2015 Coll., with is specifies technical requirements for medical devices (Directive 93/42/EEC)
- 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)

**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 ISO 14971:2012, EN ISO 10993-5:2009, EN ISO 10993-10:2013

Place and date of declaration issue: Slaný, 1.3.2019

Signed for and on behalf of **LINET spol. s r.o.**

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**Ing. Tomáš Kolář, Managing Director**



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