# EC DECLARATION OF CONFORMITY

| Number: | PSEN0031 |
|---|---|
| Version: | 04 |

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

Integrated Air Mattress system – ***OptiCare / 1VSM, 1VSK***

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

| | |
|---|---|
| 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:**

| | |
|---|---|
| Product: | **OptiCare** |
| Description and function designation: | The OptiCare mattress system is intended to aid in the prevention and treatment of pressures sores of patient.<br>The Opticare mattress can only be used when installed on a Linet Multicare or Eleganza 5 bed frame.<br>This EC conformity declaration also covers all applicable accessories approved by manufacturer. |
| 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)
- 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 60601-1-6:2010, EN ISO 14971:2012, EN ISO 10993-5:2009, EN ISO 10993-10:2013, BS 7177:2008

Place and date of declaration issue: Slaný, 1.3.2019

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

**Ing. Tomáš Kolář, Managing Director**



CE