EC DECLARATION OF CONFORMITY

Number:	PSEN0017
Version:	03

1. Product - instrument Type / Model:

Active integrated mattress replacement system – ***Symbioso / 1VS, 3VS***

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:	**Symbioso**
Description and function designation:	Active integrated mattress replacement system (alternating pressure), intended for use as an accessory of hospital bed Multicare.
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 60601-1-6:2010, EN ISO 10993-5:2009, EN ISO 10993-10:2013 and EN ISO 14971:2012

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

CE