

EC DECLARATION OF CONFORMITY

Number: PSEN0001

Version: 04

**1. Product - instrument Type / Model:**Active mattress replacement system – *Air2Care / 1VA***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:	Air2Care
Description and function designation:	Active mattress replacement system (alternating pressure). 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 60601-1-2:2007, EN 60601-1-6:2010, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 14971:2012

Place and date of declaration issue: Slaný, 20.07.2018

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

Ing. Tomáš Kolář, Managing Director