

# EC DECLARATION OF CONFORMITY

Number:

PSEN0022

Version:

02

## 1. Product - instrument Type / Model:

Passive preventive antidecubitus mattress – *EffectaCare, CliniCare, PrimaCare / 4PP*

## 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:	<b>EffectaCare, CliniCare, PrimaCare</b>		
	EffectaCare 10	CliniCare 10	PrimaCare 10
	EffectaCare 20	CliniCare 20	PrimaCare 20
		CliniCare 30	
	<b>4PP</b>		
Description and function designation:	Passive preventive antidecubitus mattress for medical, nursing and home care. This EC conformity declaration also covers all applicable accessories.		
Classification of the product as the medical device:	<b>Class I non sterile, without measuring function, according to annex IX of Government Order No.54/2015 Coll. (MDD 93/42/EEC) – rule 1</b>		

## 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 ISO 10993-5:2009, ISO 10993-10:2013 and non-harmonized technical standards: BS 7177:2008, EN 597-1:2015, EN 597-2:2015

Place and date of declaration issue: Slaný, 20.07.2018

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

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Ing. Tomáš Kolář, Managing Director