ANNEX B – DECLARATION OF CONFORMITY

We declare, under our sole responsibility, that the product listed below conforms to the provisions of:

- The European Council Directive 93/42/EEC of 21 Sept 2007 concerning medical devices
- The European Council Directive 2012/19/EU of 04 July 2012 concerning electronic waste
- The European Council Directive 2011/65/EU of 08 Jun 2011 concerning restriction of hazardous substances

Manufacturer's Name and Business Address	International Biophysics Corporation 2101 E. St. Elmo Rd Suite 275 Austin, TX 78744 USA			
EC REP	QNET B.V. Kantstraat 19 NP Haaren The Netherlands			
Product Name	AffloVest			
REF	Catalog Number	Description	Catalog Number	Description
	8100XXS	Percussive vest	8300	Percussive vest
	8100XS	Percussive vest	8300XL	Percussive vest
	8100	Percussive vest	8300XXL	Percussive vest
	8200	Percussive vest		
Conformity Assessment Route Annex	V Section 3			
Medical Device Classification	IIa			
Medical Device Classification Rules	9			
GMDN Code and Term	45292, Chest-percussion airway secretion-clearing system			
Notified Body CE 0459	GMED SAS 1 rue Gaston Boissier 75015 PARIS FRANCE EC-Certificate No. 30905			
Standards Applied:	Standard Number	Description		
	EN ISO 13485:2016	Medical devices—Quality management systems—Requirements for regulatory purposes		
	EN ISO 15223-1:2016	Symbols for use in the Labeling of Medical Devices		
	EN ISO 14971:2012	Medical devices – Application of risk management		
	IEC 62304:2006+A1:2015	Medical device software – Software life cycle processes		
	IEC 60601-1: (3.1 edition) + A1 2012 and/or EN 60601-1 (2006 edition) + A12 2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance		
	EN 60601-1-2:2007, inc. AC:2010 and/or ANSI/AAMI 60601-1-2 (4th edition)	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility – Requirements and tests		
	EN 60601-1-11:2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment		
	IEC/EN 60529:2013	Degrees of protection provided by enclosures		

Authorized Signatory:

13 January 2020

Geoff Marcek – Management Representative