

EU Declaration of Conformity

We

BeWellInnovations NV

Lievevrouwestraat 10

B-2520 Ranst

Belgium

hereby declare under our sole responsibility that “**SelfTest kiosk**” is placed on the market as a system/procedure pack in compliance with article 12 of EC 93/42/EEC, as amended by Directive 2007/47/EC, and consists of the following medical devices:

Item code	System/ procedure pack – brand name	Item code	Medical device – brand name	CE certificate number & classification	Manufacturer
1000010	SelfTest kiosk	0100001	Well@Home – Remote patient monitoring and follow- up	N/A (class I)	BeWell Innovations Lievevrouwestraat 10 B-2520 Ranst Belgium
		3231	Nonin® Finger Pulse Oximeter	G01 024497 0030 (class IIb)	Nonin Medical, Inc. 13700 1 st Avenue North Plymouth MN 55441-5543 USA
		TM- 2657P	Blood pressure monitor	G1 085349 0009 (class IIa)	A&D Company, Limited 1-243 Asahi, Kitamoto-shi, Saitama-ken 364- 8585 Japan

The devices/components included in the systems/procedure packs are put together within their intended purposes and within the limits of use specified by the manufacturers.

BeWellInnovations declares that

- a) we have verified their mutual compatibility in accordance with the manufacturers' instructions and have carried out our operations in accordance with these instructions; and
- (b) we have packaged the system and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
- (c) the whole activity is subjected to appropriate methods of internal control and inspection.

Date of first version: 31/01/2016

Ranst, Belgium: 25/10/2021

Joris Wille, CEO