

## DECLARATION OF CONFORMITY

We, **elem6 s.r.o.**,

declare, under our sole responsibility, that the product

**Product name:** TrueLife

**Model No.:** Pulse

**Serial No.:** TLPULSEYYMMXX

*(TLPULSE = prefix, YY = production year, MM = production month, XX = batch number)*

**Classification:** Class IIa, Rule 10

we are the importer of to the EU, has been tested with the listed standards and found in compliance with the Medical Devices Directive **93/42/EEC**.

This declaration was issued based on EC certificate prepared by:

SGS Belgium NV  
Noorderlaan 87 BE-2030 Antwerpen  
Belgium

**Certificate No.:** CN20/42012

**Test Standards:** EN60601-1:2006+A1:2013, EN60601-1-2:2015, ENISO10993-1:2009/AC:2010, EN62304-2006:AC:2008, EN80601-2-30:2010+A1:2015, EN60601-1-11:2015, EN62366:2008, EN1060-1:1995+A2:2009, EN 1060-3:1997+A2:2009, ENISO10993-5:2009, ENISO10993-10:2013, ENISO13485:2016, ISO81060-2, EN ISO14971:2012, EN ISO15223-1:2016

# CE 1639

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