

## DECLARATION OF CONFORMITY

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

declare, under our sole responsibility, that the product

**Product name:** TrueLife

**Model No.:** Pulse B-Vision

**Serial No.:** TLPBVYYMMXXXXX

*(TLPBV = prefix, YY = production year, MM = production month, XXXXX = product 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:

TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 Munich, Germany

Certificate No.: **G2 090084 0007 Rev. 00**

Test Standards: **EN ISO 13485:2016, ISO 14971:2019, IEC 60601-1:2005+A1:2012  
IEC 60601-1-2:2014, ISO 10993-1:2009, ISO 10993-5:2009  
ISO 10993-10:2010, IEC 80601-2-30:2013, IEC 62304:2006+A1:2015  
IEC 62366-1:2015/Cor 1:2016, EN 62366-1:2015+AC:2015,  
EN 1041:2013+A1:2013, MEDDEV2.7.1 Rev. 4, IEC 60601-1-11:2015,  
ISO 14155:2011/Cor 1:2011, EN ISO 15223-1:2017,  
EN ISO 81060-1:2012, ISO 81060-2:2018**

# CE 0123

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