



## Declaration of Conformity

<b>Manufacturer</b>	DELBio, INC.
<b>Place of manufacturer</b>	3, 7F, NO.252, SHANGYING RD., GUSHAN DIST., TAOYUAN CITY, 333, TAIWAN.
<b>Product</b>	DELBio Fingertip Pulse Oximeter (Model: DB12) SPENGLER Pulse oximeter (Model: OXYGO)
<b>GMDN code</b>	17148
<b>Classification</b>	Class IIa, according to Directive of 93/42/EEC, Annex IX
<b>Conformity assessment Route</b>	Council Directive 93/42/EEC, Annex II Full Quality Assurance System, excluding section 4
<b>Applied standard</b>	EN ISO 13485:2016, EN ISO 14971:2012, EN 60601-1:2006/A1:2013/ A12:2014, EN 60601-1-2:2015, EN 60601-1-6:2010/A1:2015, IEC 60601-1-11:2015, EN ISO 9919:2009, ISO 80601-2-61:2017, EN ISO 14155-1:2012, EN ISO 10993-1:2009+AC:2010, EN ISO 10993-5:2009, ISO 10993-10: 2010, EN ISO 15223-1:2016, IEC 60878: 2015, EN 62304:2006+A1:2015, IEC 60068-2-64: 2008, EN 62366-1:2015, EN ISO 17664:2017, IEC/TR 80002-1:2009, EN ISO 17100:2015+A1:2017, Council Directive 93/42/EEC, Directive 2002/96/EC, Directive 2011/65/EU
<b>EU representative</b>	Delta Electronics (Netherlands) B.V. Zandsteen 15, 2132 MZ Hoofddrop, The Netherlands
<b>Notified Body</b>	TÜV Rheinland LGA Products GmbH Tillystraße 2, D-90431 Nürnberg
<b>EC certificate No</b>	CE0197 Certificate no: HD 60137550 0001

We herewith declare that the above-mentioned product(s) meet the provisions of Council Directive for 93/42/EEC (Annex II Full Quality Assurance System). The Manufacturer retains all supporting documentation.

Taoyuan, Taiwan, 2019/3/29

Place and date of issue

Chairman