

Declaration of Conformity

We,



Spiracle Technology, LLC
10601 Calle Lee #190
Los Alamitos, CA 90720 U.S.A

declare that the products listed on this document (below):

Item: Fingertip Pulse Oximeter (PEZO2) & RELATED ACCESSORIES
Product: FERNO2 - PEZO2 Fingertip Pulse Oximeter, P/N T10565

PEZO2 Fingertip Pulse Oximeter

Mfg. for Spiracle Technology
Pulse Oximeter and SpO2 Probe
Model: AE-XX, AH-XX and ASXXX-XX

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Low of Member States concerning Medical Device Directive 93/42/EEC- M5(2007/47/EC)

For the evolution regarding the Class IIb product safety aspects, the following standards were applied:

EN ISO 14971:2012; Medical devices. Application of risk management to medical devices

- **EN ISO 15223-1:2016; Symbols to be used with medical device labels, labeling and information to be supplied—Part1: General requirement**
- **EN 1041:2008; Information supplied by the manufacturer of medical devices**
- **EN 60601-1:2006/A1:2013; Medical electrical equipment; Part1: General requirements for safety**
- **EN 60601-1-2:2015 (EN 60601-1-2:2007); Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests**
- **EN 62304:2006/AC:2008; Medical device software – Software life cycle processes**
- **EN 62366:2008; Medical devices - Application of usability engineering to medical devices**
- **ISO 80601-2-61:2011; Medical electrical equipment. Particular requirements for basic safety and essential performance of pulse oximeter equipment**
- **EN ISO 10993-1:2009/AC: 2010: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process**
- **EN/ISO 13485: 2012 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes**
- **RoHS Directive 2011/65/EU: Restriction of the Use of Certain Hazardous Substances in Electronic and Electrical Equipment**

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Notified Body: DNV GL Presafe AS



following the provisions of Directive 93/42/EEC as amended by 2007/42/EC, Annex I, Annex V, Annex VII
Issued at,

Spiracle Technology, LLC
10601 Calle Lee #190
Los Alamitos, CA 90720 U.S.A

Michael Sarné, Managing Director

April 20, 2020

Date