

# Declaration of Conformity

We,

**Spiracle Technology**

10601 Calle Lee, #190

Los Alamitos, CA 90720 U.S.A.

Tel: (714) 418-1091 Fax: (714) 418-1095

Declare that the product(s) listed below:

	Finger Pulse Oximeter	
<b>Product</b>	PEZO2 Finger Pulse Oximeter	
<b>Model</b>	T10565	
<b>Type/Group</b>	Refer to Below Codes Listing	
<b>Item No.</b>	<b>Name</b>	<b>Codes Listing No.</b>
1	Spiracle Technology, FERNO2, PEZO2 Finger Pulse Oximeter	T10565

which this declaration relates, is in conformity with the following standards or other normative documents :

#### STANDARD/REQUIREMENTS

EN ISO 13485

EN ISO 14971:2019

EN ISO 10993-1:2018

EN ISO 15223-1:2021

EN ISO 80601-2-61:2017

EN 62366-1:2015

IEC 60601-1:2005 (3<sup>rd</sup> Edition)

IEC 60601-1-2:2014 (4<sup>th</sup> Edition)

IEC 62304:2006/Amd 1:2015

CE MDD: Cert. by mfg.

2007/47/EC

FDA 510(k)

Class 1 - Not Applicable (exemption)

CE

Class 1, Rule 1, Annex VIII, Regulation (EU) 2017/745

Issued by,

**Spiracle Technology**

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Los Alamitos, CA 90720 U.S.A.

Date: 01-16-2025



Michael Sarné

Managing Director