



## Declaration of Conformity

Tobii Dynavox, a business unit and subsidiary of Tobii AB, hereby declares that the product identified herein complies with the following directives:

### EU Directives

- Regulation (EU) 2017/745 Medical Device Regulation (MDR), accessory only Article 2 (2).
- EN 62471 Photobiological Safety of Lamps
- 2011/65/EU Restrictions of Hazardous Substances Directive (RoHS 2)
- Regulation 2014/30/EU Electromagnetic Compatibility Directive (EMC)
- EN 62368-1:2014 CB (incorporates LVD) Electronic Safety (CB Scheme)
- IEC 60950-1:2005 Electronic Safety (CB Scheme)
- REACH and WEEE Directives

### Product Information & Use

Type of product: **Eye Tracker**

Product name/Model: **Tobii Dynavox PCEye 5 Gen**

Product description: **The PCEye gen 5 is a clip-on eye tracker that lets you access and control your computer using only your eyes.**

Intended use: **The PCEye 5 Gen is intended to be used for Computer Control for Augmentative and Alternative Communication (AAC) and/or for computer access purposes as an alternative input device to the keyboard and mouse for people that have challenges in their ability to speak and/or access a computer due to injury, disability or illness.**

### Other Directives & Standards

- Federal Communications Commission (FCC), CFR Title 47, Part15
- Industry Canada Equipment Standard (ICES-003), Issue 6: 2016
- VCCI-CISPR 32: 2016, Class B.

The following standards have been used:

- ISO 14971:2007+2012 (Medical Device Risk Mgmt.)
- EN 55035:2017
- EN 55032: 2015
- IEC 60068-2-64, 27, 31:2008 (Shock/Vibe/Fall)

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all essential requirements.

DocuSigned by:

*Bob Cunningham*

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Robert Cunningham, VP of Product Development

Signed in Pittsburgh, Pennsylvania USA

9/25/2020

Date

*DocuSign used due to COVID-19 Pandemic.*

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