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, Part 15
- 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.

Robert Cunningham, VP of Product Development
Signed in Pittsburgh, Pennsylvania USA

Date 9/25/2020

*DocuSign used due to COVID-19 Pandemic.*