tobii dynavox

Declaration of Conformity

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

EU Directives

- 93/42/EED Medical Device Directive (MDD), as amended 2007/47/EC, Annex IX, Rule 12
- 2014/53/EU Radio Equipment Directive (RED)
- 2011/65/EU Restrictions of Hazardous Substances Directive (RoHS 2)
- 2004/30/EU Electromagnetic Compatibility Directive (EMC)
- 2014/35/EU Low Voltage Directive (LVD)
- UN 38.3 IATA
- REACH and WEEE Directives

Product Information & Use

Type of product: **Speech Generating Device**

Product name/Model: **Tobii Dynavox Indi 7**

Product description: **7" AAC Speech Generating Device (SGD), custom designed to meet needs of individuals who cannot speak.**

Intended use: **The Tobii Dynavox Indi 7 is a Windows SGD, including communication software for people that have challenges in their ability to speak due to injury, disability or illness.**
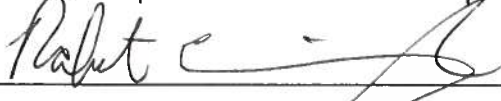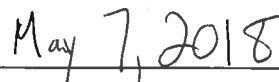
Other Directives & Standards

- Federal Communications Commission (FCC), CFR Title 47, Part15 Subpart B: 2015, CLASS B
- ANSI C 63.4-2014
- Industry Canada Equipment Standard (ICES-003), Issue 6: 2016 Class B

The following standards have been used:

- ISO 14971:2007+2012 (Medical Device Risk Mgmt.)
- IEC 60601-1:2012
- EN 55032: 2015
- EN 55024: 2010+A1:2015
- EN 61000-3-2:2014
- EN 61000-3-3:2013
- EN 62479: 2010

- EN 62368-1:2014 (Second Ed.)
- ETSI EN 300 328/440
- ETSI EN 301 489-1, 489-3, 489-17, 489-19, 893
- ETSI EN 303 413
- EN & IEC 62209-1:2010
- EN 50566:2013
- EN 50663:2017

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.

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Robert Cunningham, VP of Product Development

May 7, 2018

Date

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