

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

- 2017/745 Medical Device Regulation (MDR), effective 26/05/2021, Annex VII, Class 1, Rule 13
- 93/42/EEC Medical Device Directive (MDD), as amended 2007/47/EC, Annex IX, Class 1, 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** Device Identifier 7340074601042

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.**

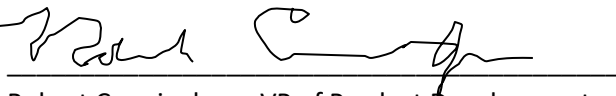
Other Directives & Standards

- ISO 13485:2016 Quality System Registered
- 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.



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

February 16, 2021

Date

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