

Declaration of Conformity

EC Directives

We, Tobii Dynavox, hereby declare that the product identified herein complies with the following directives:

- **Medical Device Regulation (MDR)**
- **Radio Equipment Directive (RED)** 2014/53/EU
- **Low Voltage Directive (LVD)** 2014/35/EU
- **REACH Directive** 2006/121/EC, 1907/2006/EC Annex 17
- **Electromagnetic Compatibility (EMC)** 2014/30/EU
- **RoHS2 Directive** 2011/65/EU
- **WEEE Directive** 2012/19/EU

Type of product: Tablet PC

Product name/model: Tobii Dynavox I-110

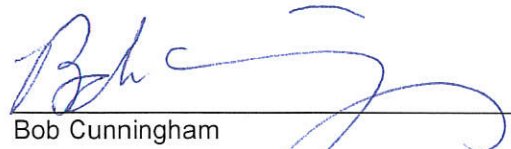
Product Description: AAC Speech Generating Device (SGD), custom designed to meet needs of individuals who cannot speak.

Intended use: The Tobii Dynavox I-110 is a Windows SGD, including communication software for people that have challenges in their ability to speak due to injury, disability or illness.

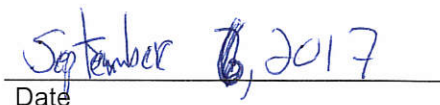
The following standards are used for CE compliance:

- ISO14971:2007+2012 (Medical Devices Risk Mgmt)
- EN 60601-1:2006+A11:2011+A1:2013+A12:2014 (Safety)
- EN 60601-1-11:2015 (Safety)
- IEC 60950-1:2005 (2nd edition)+A1:2009+A2:2013
- EN 60950-1:2006+A11:2009+A1:2010+A12:2011+A2:2013
- IEC 62368-1:2014 (2nd edition) (Safety)
- EN 62366:2008+A1:2015 (Usability)
- EN 50566:2013 (SAR)
- EN 62209-2:2010 (SAR)
- EN 62479:2010 (SAR)
- EN 55011:2009+AC:2010/Class B (EMC)
- EN 60601-1-2:2015 (EMC)
- EN 61000-2-3:2014/Class D (EMC)
- EN 61000-3-3:2013 (EMC)
- EN 55032:2012/AC:2013 (EMC)
- EN 55024:2010 (EMC)
- ETSI EN 301 489-1 V2.1.1 (2017-02) (EMC)
- ETSI EN 301 489-3 V2.1.1 (EMC)
- ETSI EN 301 489-17 V3.1.1 (2017-02) (EMC)
- ETSI EN 300 328 V2.1.1 (2016-11) (RF)
- ETSI EN 300 440 V2.1.1 (2017-03) (RF)
- ETSI EN 300 893 V2.1.0 (2017-03) (RF)

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.


Bob Cunningham

VP of Products and Development
Tobii Dynavox


Date

Tobii AB
Box 743
S-182 17 Danderyd
Sweden

phone: +46 8 663 69 90
fax: +46 8 30 14 00
www.tobii.com