

Declaration of Conformity

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

- **Medical Device Directive (93/42/EEC) Class I, Rule 12** (and Medical Device Regulation (EU) 2017/745 effective 26/05/2020, Class I, Rule 13)
- **Radio Equipment Directive (RED) 2014/53/EU**
- **Electromagnetic Compatibility (EMC) 2014/30/EU**
- **REACH Directive 2006/121/EC, 1907/2006/EC Annex 17**
- **UN38.3 (Battery)**
- **Low Voltage Directive (LVD) 2014/35/EU**
- **RoHS 3 Directive (EU 2015/863)**
- **Battery Directive 2013/56/EU**
- **WEEE Directive 2012/19/EU**

Type of product: Portable PC

Product name/model: Tobii Dynavox I-16. Device UDI 7340074601110

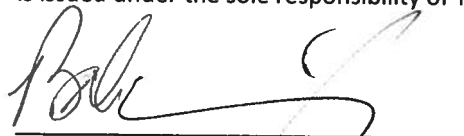
Product Description: Tobii Dynavox I-16 is a Windows-based computer designed to meet the needs of individuals who cannot speak due to injury, disability or illness. The unit comes with a 15,6-inch touch screen, communications software and optional eye control, to provide a better quality of life for people with reduced physical ability.

Intended use: The Tobii Dynavox I-16 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 relevant standards are used for EU conformity:

- ISO14971:2007 (Medical Devices Risk Mgmt)
- Medical Device Directive (93/42/EEC) EN 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012. The product fulfils the requirements of EN 60601-1:2006/A11:2011/A1:2013/A12:2014
- IEC 60950-1:2005 (2nd edition)+A1:2009+A2:2013
- EN 60950-1:2006+A11:2009+A1:2010+A12:2011 +A2:2013
- IEC 62366:2015 (Usability)
- IEC 60601-1-EN 60601-1-2:2015 (EMC)
- ETSI EN 301 489-1-17/ETSI EN 301 489-19 (EMC)
- ETSI EN 300 328 V2.1.1 (2016-11) (RF)
- ETSI EN 303 413 v1.1.1:2017 (GPS)
- ETSI EN 301 893 V2.1.0 (2017-03) (RF)
- EN 50566:2013 (SAR)
- EN 62209-2:2010 (SAR)
- EN 62479:2010 (SAR)

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. This Declaration of Conformity is issued under the sole responsibility of Tobii Dynavox AB, a business unit of Tobii AB.



Bob Cunningham

VP of Products and Development

Tobii Dynavox

A business unit of Tobii AB

Nov. 25 2019
Date