

Declaration of Conformity

Under the sole responsibility of Tobii Dynavox, SRN SE-MF-000008884, we hereby declare that the product identified herein complies with the following directives and standards::

- **Medical Device Directive (93/42/EEC) Class I, Rule 12** and **Medical Device Regulation (EU) 2017/745** effective 26/05/2021, **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)**
- **Electrical Safety Medical (IEC 60601)**
- **Low Voltage Directive (LVD) 2014/35/EU**
- **RoHS 3 Directive (EU 2015/863)**
- **Battery Directive 2013/56/EU**
- **WEEE Directive 2012/19/EU**
- **Electrical Safety IT/AV (IEC 62368)**

Type of product: Speech Generating Device

Product name/model: Tobii Dynavox I-16, Product #12007770, 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 62368-1 (Electrical Safety IT/AV)
- 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)

DocuSigned by:



9AC6C668A75E424...

Anthony Pavlik

Chief Operating Officer

Tobii Dynavox LLC & Tobii Dynavox AB

12/20/2021

Date

Signed in Pittsburgh, Pennsylvania USA