



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 Regulation** (EU) 2017/745 effective 26/05/2021, **Class I, Rule 13**
- **Low Voltage Directive** (LVD) 2014/35/EU (incl. in IEC 62368)
- **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 Transport)**
- **Electrical Safety Medical 93/42/EEC** (IEC 60601)
- **RoHS 3 Directive** (EU 2015/863)
- **Battery Directive** 2013/56/EU
- **WEEE Directive** 2012/19/EU
- **Electrical Safety IT/AV** (IEC 62368-1)

Type of product: Speech Generating Device

Product name/model: Tobii Dynavox TD I-110, Product # 12009007, Device UDI 7340074601714

Product Description: Tobii Dynavox TD I-110 is a Windows-based computer designed to meet the needs of individuals who cannot speak due to injury, disability or illness. The durable, portable unit comes with touch screen and communications software, to provide a better quality of life for people with difficulty communicating.

Intended use: The Tobii Dynavox TD 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 relevant standards are used for EU conformity:

- ISO14971:2019 (Medical Devices Risk Management)
- ISO 13485:2016 (Quality System Registered)
- Medical Device Directive (93/42/EEC) EN 60601-1
- IEC 62366-1 (Usability)
- IEC 60529 Ed. 2.2: 2013 (Ingress Protection)

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Anthony Pavlik

Chief Operating Officer

Tobii Dynavox LLC & Tobii Dynavox AB

12/21/2021

Date

Signed in Pittsburgh, Pennsylvania